Docket for 03-388

(27)

No. 03-388
Title: Dennis Bates, et al., Petitioners
v.
Dow Agrosciences LLC
Docketed: September 12, 2003
Lower Ct: United States Court of Appeals for the Fifth Circuit
Case Nos.: (02-10908)
Decision Date: June 11, 2003
Questions Presented

Date	Proceedings and Orders
Sep 9 2003	Petition for writ of certiorari filed. (Response due October 14, 2003)
Sep 30 2003	Order extending time to file response to petition to and including November 13, 2003.
Nov 13 2003	Brief of respondent Dow Agrosciences LLC in opposition filed.
Nov 25 2003	DISTRIBUTED for Conference of December 12, 2003.
Dec 15 2003	The Solicitor General is invited to file a brief in this case expressing the views of the United States.
May 28 2004	Brief amicus curiae of United States filed.
Jun 4 2004	Supplemental brief of petitioners Dennis Bates, et al. filed. (Distributed)
Jun 8 2004	DISTRIBUTED for Conference of June 24, 2004.
Jun 18 2004	Supplemental brief of respondents Dow Agrosciences LLC filed. (Distributed)
Jun 28 2004	Petition GRANTED.
Jul 13 2004	Extension of time within which to file the joint appendix and petitioners' brief on the merits to and including September 13, 2004.
Jul 29 2004	Record received from U.S.C.A. 5th Circuit (U.S.D.C. for Northern Dist. of Texas record included) (2 boxes)
Sep 1 2004	Consent to the filing of amicus briefs in support of either party received from counsel for the petitioners.
Sep 10 2004	Consent to the filing of amicus briefs in support of either party received from counsel for the respondent.
Sep 13 2004	Brief amici curiae of Natural Resources Defense Council, et al. filed.
Sep 13 2004	Brief of petitioners Dennis Bates, et al. filed.
Sep 13 2004	Joint appendix filed.
Sep 13 2004	Brief amici curiae of Western Peanut Growers Association, et al. filed.
Sep 13 2004	Brief amici curiae of Texas, et al. filed.
Sep 13 2004	Brief amicus curiae of Association of Trial Lawyers of America filed.
Sep 13 2004	Brief amicus curiae of Herbert Samuel Harrison filed.
Sep 22 2004	Extension of time within which to file respondent's brief on the merits to and including November 17, 2004.
Oct 27 2004	Further extension of time within which to file respondent's brief on the merits to and including November 24, 2004.
Nov 12 2004	SET FOR ARGUMENT ON Monday, January 10, 2005.
Nov 12 2004	CIRCULATED.
Nov 23 2004	Brief amicus curiae of Chemistry Council filed. (Distributed)

Nov 24 2004	Brief of respondent Dow Agrosciences LLC filed. (Distributed)
Nov 24 2004	Brief amicus curiae of Texas Chemical Council filed. (Distributed)
Nov 24 2004	Brief amicus curiae of Edwin L. Johnson filed. (Distributed)
Nov 24 2004	Brief amicus curiae of Croplife America and National Pest Management Association filed. (Distributed)
Nov 24 2004	Brief amicus curiae of Washington Legal Foundation filed. (Distributed)
Nov 24 2004	Brief amicus curiae of E.I. Du Pont De Nemours and Company, Monsanto Company, and Syngenta Crop Protection, Inc. filed. (Distributed)
Nov 24 2004	Brief amicus curiae of Defense Research Institute filed. (Distributed)
Nov 24 2004	Brief amicus curiae of United States filed. (Distributed)
Nov 24 2004	Brief amicus curiae of Product Liability Advisory Council, Inc. filed. (Distributed)
Nov 24 2004	Brief amicus curiae of Chamber of Commerce of the United States filed. (Distributed)
Nov 24 2004	Brief amicus curiae of BASF Corporation filed. (Distributed)
Nov 29 2004	LODGING of respondent, consisting of a bound volume containing two documents, "Public Interest Document for Products Containing Diclosulam" (1996) and "Reduced Risk Rationale for Diclosulam Herbicide Used in Control of Broadleaf Weeds in Peanuts, (1998) approved and received. (Distributed)
Dec 6 2004	Motion of the Acting Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument filed.
Dec 10 2004	Motion of Texas, et al. for leave to participate in oral argument as amicus curiae and for divided argument filed.
Dec 13 2004	Motion of the Acting Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument GRANTED.
Dec 17 2004	Letter received from counsel for petitioner in opposition to motion of Texas.
Dec 20 2004	Letter received from counsel for Texas in response to petitioner's letter opposing the motion of Texas.
Dec 29 2004	Reply of petitioners Dennis Bates, et al. filed. (Distributed)
Jan 6 2005	Letter dated January 5, 2005 received from counsel for the respondent. (Distributed).
Jan 7 2005	Motion of Texas, et al. for leave to participate in oral argument as amicus curiae and for divided argument DENIED.
Jan 10 2005	Argued. For petitioners: David C. Frederick, Washington, D.C. For respondent: Seth P. Waxman, Washington, D.C.; and on behalf of the United States, as amicus curiae, Lisa S. Blatt, Assistant tot he Solicitor General, Department of Justice, Washington, D.C.

Supreme Court, U.S.
FILED

03-388 SEP 9 2003

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IN THE

Supreme Court of the United States

DENNIS BATES; JIMMY BURSON; BENNY JUDAH, doing business as CLEARWATER FARMS; TOMMY COLEMAN; RICHARD COX; WAYNE DAVIS; NEIL FRIESSEN; JAKE FORESE; THOMAS FUSTON; ARTHUR GALVAN, doing business as G-5 PARTNERSHIP; GREG HUGHES; SANDRA AND KARL DON HUGHES doing business as JH CATTLE CO.; RUDY KLASSEN; RONNIE LOVE; KEVIN MATHIS; BRAD PALMER; KIRK PARRISH, doing business as K-L FARMS; JERRY PARRISH; JoEVELYN PATTERSON and DONALD GRUBEN; STACEY PRICE; BENNY JUDAH doing business as PROGRESSIVE FARMS; MORRIS RUSHING, doing business as PEA-COT FARMS; BILLY SHANNON, FLOYD STOKES; CRAIG WEST; FRENCHIE LEE WHEELER

Petitioners,

v.

DOW AGROSCIENCES LLC,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Which, if any, state law crop injury claims are preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-137?

STATEMENT PURSUANT TO RULE 29.6

None of the corporate Petitioners has a parent company and no publicly held company owns 10% or more of the stock of any such corporate Petitioner.

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Appendix A — Opinion Of The United States Court Of Appeals For The Fifth Circuit Filed June 11, 2003 ..... 1a

Appendix B — Order Of The United States District Court For The Northern District Of Texas, Lubbock Division Dated And Filed June 3, 2002 ..... 21a

Petitioners respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit in this case.

OPINIONS BELOW

The district court's opinion (per Cummings, D.J.) granting respondent's summary judgment motion (Appendix ("Pet. App.") 21a-31a) is published at 205 F. Supp. 2d 623. The opinion of the court of appeals (per Feldman, D.J. (District Judge of the Eastern District of Louisiana, sitting by designation), joined by Garwood and Higginbotham, JJ.) affirming (Pet. App. 1a-20a) is published at 332 F.3d 323.

STATEMENT OF THE JURISDICTION

The court of appeals entered its order and opinion on June 11, 2003. Petitioners invoke this Court's jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

7 U.S.C. § 136v provides as follows:

> **Authority of States**
>
> **(a) In general**
>
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.
>
> **(b) Uniformity**
>
> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

STATEMENT OF THE CASE

The need for clarification by this Court in this area of federal preemption has never been more evident than in the facts presented by this case. Petitioners are farmers from west and northwest Texas who purchased and applied Strongarm to prevent weeds in their peanut crops. Strongarm, a recently

released herbicide manufactured by Dow Agrosciences LLC ("Dow"), was the only herbicide applied to the farmers' crops in the 2000 growing season. After each farmer experienced stunted peanut growth and reduced crop yield, they retained counsel to prepare a state lawsuit in the various counties where the farmers resided. Pretrial discovery indicated that Strongarm causes injury to peanut roots in soils with pH levels of 7.0 or greater, and that before the herbicide's release, Dow was aware of the harmful effect of applying Strongarm to peanuts grown in the high pH-level soils of Texas, New Mexico, and Oklahoma.

The Texas Deceptive Trade Practices Act ("DTPA") governs such claims and requires a plaintiff to give a defendant sixty days notice of the complaint before filing suit. After receiving the notice required by state law, and during the sixty day period in which the farmers' were prohibited from filing suit, Dow filed a declaratory judgment action in federal district court in Lubbock, Texas for the sole purpose of declaring the validity of its affirmative defenses. The farmers contested the federal court's jurisdiction and filed a motion to dismiss. Upon denial of that motion, the farmers filed a counterclaim, raising the state law tort claims of breach of warranty, fraud, defective design, negligence, and violations of the DTPA against Dow. The district court dismissed the farmers' claims on motion for summary judgment by Dow, finding the state law tort claims were preempted by the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA").

The farmers appealed the ruling to the United States Court of Appeals for the Fifth Circuit, arguing that the district court lacked jurisdiction and that FIFRA did not preempt their state law tort claims. The Fifth Circuit affirmed. Regarding the jurisdiction challenge, the court held that jurisdiction was proper because the amount in controversy for each farmer exceeded $75,000. The court also held that although Dow engaged in some degree of forum shopping, the district court correctly conducted its abstention analysis under the Declaratory Judgment Act. Regarding the FIFRA issue, the Fifth Circuit

held that because liability on these claims would induce Dow to change its product or label, the farmers' causes of action were label-related and thus, expressly preempted.

The farmers respectfully petition this Court to review the holding of the Fifth Circuit.

REASONS FOR GRANTING THE PETITION

Petitioners respectfully request this Court grant their Petition for Writ of Certiorari to clarify the confusion surrounding the preemption clause in FIFRA. Relevant case law conflicts in two ways. First, federal and state courts are at odds regarding whether FIFRA's preemption clause, found at 7 U.S.C. § 136v(b), preempts state law tort claims. Second, among the courts holding that FIFRA does preempt tort claims, there exists disagreement as to the appropriate analysis to apply in determining which, if any, tort claims are preempted by the clause. The lack of clarity has left the judiciary struggling to interpret the ambiguous statutory language. After two decades of conflicting case law, the issue has sufficiently percolated throughout the judicial system without resolution, necessitating guidance from this Court.

I. *Introduction*

This case presents this Court with the proper disposition and set of facts with which it may resolve the plethora of contradictory case law regarding the scope of the preemption clause in FIFRA. Since Congress enacted FIFRA, the judiciary has struggled to interpret the preemption provision, section 136v, leading to a "jurisprudential mare's nest."[1] These opinions, attempting to apply this Court's mandates in *Cipollone v. Liggett*

1. A substantial body of federal and state case law conflicts on the issue of whether FIFRA completely preempts tort law claims. *Compare Dow Agrosciences LLC v. Bates*, 332 F.3d 323, 333 (5th Cir. 2003) (holding FIFRA preempts state law tort claims), and *Etcheverry v. Tri-Ag Serv., Inc.*, 993 P.2d 366 (Cal. 2000) (same), *with Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir. 1984) (holding FIFRA does not preempt state law tort claims), *and Am. Cyanimid Co. v. Geye*, 79 S.W.3d 21 (Tex. 2002) (same).

Group, Inc., 505 U.S. 504 (1992) and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), have resulted in a vast array of holdings and a variety of analyses applied in the interpretation of the FIFRA preemption clause. A majority of federal courts hold that FIFRA preempts state law tort claims,[2] while many state courts, protective of their common law claims, hold the opposite.[3] In essence, the confusion surrounding FIFRA has pitted federal judges against state judges.

The long-standing controversy over the breadth of FIFRA's preemption clause prompted the Environmental Protection Agency ("EPA"), the agency authorized to enforce FIFRA, to speak out as to its interpretation of Congress's intent. OFFICE OF PESTICIDE PROGRAMS, U.S. EVTL. PROT. AGENCY, PESTICIDE REGULATION NOTICE 96-4 (June 3, 1996). When its voice went unheeded, the EPA entered the judicial fray by filing an amicus brief in conjunction with the Office of the Solicitor General.[4] In this brief, the EPA and the Solicitor General aligned with the state courts calling for a narrow interpretation of FIFRA's preemption clause. Recently, however, the Solicitor General

2. Several circuit courts have held that section 136v(b) expressly preempts any label-related damages claims, including those based upon failure to warn. *See Netland v. Hess & Clark, Inc.*, 284 F.3d 895 (8th Cir. 2002); *Hawkins v. Leslie's Pool Mart, Inc.*, 184 F.3d 244 (3d Cir. 1999); *Andrus v. AgrEvo USA Co.*, 178 F.3d 395 (5th Cir. 1999); *Kuiper v. Am. Cyanamid Co.*, 131 F.3d 656 (7th Cir. 1997); *Grenier v. Vt. Log Bldgs., Inc.*, 96 F.3d 559 (1st Cir. 1996); *Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555 (9th Cir. 1995); *Lowe v. Sporicidin Int'l*, 47 F.3d 124 (4th Cir. 1995); *Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir. 1993); *Ark.-Platte & Gulf P'ship v. Van Waters & Rogers, Inc.*, 981 F.2d 1177 (10th Cir. 1993).

3. *See, e.g., Geye*, 79 S.W.3d at 29; *Sleath v. W. Mont Home Health Servs., Inc.*, 16 P.3d 1042 (Mont. 2000), *cert. denied sub nom. Dow Agrosciences LLC v. Sleath*, 534 U.S. 814 (2001).

4. Brief of Amicus Curiae the United States, *Etcheverry v. Tri-Ag Serv., Inc.*, 993 P.2d 846 (Cal. 2000) (No. 98-127) (filed on behalf of the EPA and the Environment and Natural Resources Division of the U.S. Department of Justice).

alone filed an amicus brief, asserting that it had changed its position and that it agreed with the majority of federal cases holding that FIFRA preempts state law tort claims for failure to warn. *See* Brief of Amicus Curiae the United States on Petition for a Writ of Certiorari, *Am. Cyanamid Co. v. Geye, cert. denied*, 123 S. Ct. 2637 (2003) (No. 02-367). The federal and state judiciary, along with manufacturers, retailers, and consumers of pesticides, are equally perplexed as to whether FIFRA preempts state law tort claims. This confusion leads to harm across jurisdictional lines in every state.

The need for review by this Court is underscored by the legal landscape in Texas, one of the largest agricultural-production states.[5] The opinion handed down by the Fifth Circuit in this case directly contradicts the opinion of the Supreme Court of Texas. In 2002, the Supreme Court of Texas ruled that FIFRA does not preempt the crop injury claims of strict liability, breach of express and implied warranty, and other violations of the Texas Deceptive Trade Practices Act. *See Geye*, 79 S.W.3d at 29. Importantly, the *Geye* opinion pitted Texas against another agricultural production giant, the State of California, which previously ruled that such claims were preempted by FIFRA. *Etcheverry*, 992 P.2d at 377. In the case before this Court, the Fifth Circuit rejected the analysis of the Supreme Court of Texas in *Geye* and held that FIFRA preempts the same crop injury claims. *Bates*, 332 F.2d at 330 (5th Cir. 2003).

Accordingly, as the law stands in the State of Texas, a plaintiff suing in state court is permitted to proceed on crop damage claims, whereas had the plaintiff filed the same suit in federal court or should the case be removed, the claims are preempted as a matter of law. As a result, plaintiffs and defendants alike are encouraged to forum shop because venue

5. CAROLINE S. GLEATON & CARL G. ANDERSON, *Facts About Texas & U.S. Agriculture*, The Texas Cooperative Extension, Dept. of Agricultural Economics, The Texas A&M University System (2002) (stating that California and Texas lead the nation in farm receipts and market value of agricultural products sold).

of the suit is outcome determinative. Furthermore, the problems caused by forum shopping are compounded due to the unique facts of this case, where Dow relied on the Declaratory Judgment Act to forum shop and "strike first," securing the favorable federal venue during the time the farmers complied with the state law requirements of providing Dow with sixty days notice of their claims. *Bates*, 332 F.3d at 324.

Texas is not the only state to suffer from conflicting FIFRA jurisprudence. *Compare Sleath*, 16 P.3d at 1042 (Mont. 2001) (holding FIFRA does not preempt Montana state law damages actions), *and Ciba-Geigy Corp. v. Alter*, 834 S.W.2d 136 (Ark. 1992) (recognizing that strict liability, negligence, breach of warranty, and misrepresentation causes of action under Arkansas state law not preempted by FIFRA), *with Taylor*, 54 F.3d at 562 (9th Cir. 1995) (preempting state law tort claims for strict liability, negligent testing, and breach of warranty), *and Netland*, 284 F.3d 899-900 (8th Cir. 2002) (finding preemption of state law strict liability, negligence, and failure to warn claims). Until this Court provides guidance to define where FIFRA falls in the continuum between its holdings in *Cipollone* and *Medtronic*, all parties involved in pesticide manufacturing, selling, and usage will suffer from the maze of conflicting case law. Moreover, throughout this time of confusion, FIFRA's goals of uniformity and protection of health are eviscerated. The farmers respectfully request this Court grant this Petition for Writ of Certiorari to resolve the conflict created by the lower courts.

II. *History of FIFRA*

FIFRA was originally passed as a "labeling statute" in 1947. *Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 601 (1991). Since that time, Congress has strengthened the provisions of FIFRA to address health and safety concerns regarding pesticides. *Id.* The current version of FIFRA effectuates a regulatory scheme authorizing the EPA to control the labeling, marketing, and selling of pesticides. *Id.*

A. Relevant Provisions

Under FIFRA, a pesticide may not be sold in the United States until it is registered with and its labels approved by the EPA. 7 U.S.C. §§ 136-137. After the enactment of the 1972 amendments, however, the EPA requested that Congress eliminate the requirement that it review the efficacy[6] of a product during the labeling regulation because the approval process was overly cumbersome. H.R. REP. No. 95-343 (1977), *reprinted in* 1978 U.S.C.C.A.N. 1974 (statement of EPA Administrator Douglas M. Costle). In describing the EPA's burden, the House Agriculture Committee stated, "The registration and reregistration process, which is the foundation of the program, has come to a virtual halt." H.R. REP. No. 95-663 (1977), *reprinted in* 1978 U.S.C.C.A.N. 1991.

Congress reacted to the EPA's concerns by amending FIFRA to permit the EPA to waive the inquiry into product efficacy and limit its review only to the propriety of the label:

> **Approval of registration**
>
> In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition in such as to warrant proposed claims of efficacy.

7 U.S.C. § 136a(c)(5). Since the enactment of section 136a(c)(5), the EPA has waived efficacy inquiries and limited its review to the propriety of the product label. As such, because FIFRA contains no private cause of action, state law tort suits are the only legal vehicle serving to regulate the efficacy of pesticides.

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6. The term "efficacy" has been given an assortment of meanings by various courts. As defined by the EPA, "efficacy" has two components: product performance (whether the product controls the target pest) and phytotoxicity (whether the product harms the target crop). Brief of Amicus Curiae the United States, *Etcheverry v. Tri-Ag Serv., Inc.*, 993 P.2d 846 (Cal. 2000) (No. 98-127).

Along with the provisions governing the labeling procedures, FIFRA also contains a preemption clause, limiting the rights of state courts in the area of pesticide labeling regulation. *See* 7 U.S.C. § 136v(a)-(b). These provisions are at the center of this controversy among federal courts, state courts, and the EPA. Specifically, courts have split over whether Congress intended to encompass state law tort claims within the scope of FIFRA's preemption clause.

As this Court has instructed, the "task of statutory construction must focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent." *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993). This Court has also emphasized that where the regulation contains express preemptive provisions, it is improper to infer a Congressional intent to preempt state law tort claims. *Cipollone*, 505 U.S. 504. Subsection (a) of FIFRA provides that a "State may regulate the sale or use of any federally registered pesticide . . . but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter." 7 U.S.C. § 136v(a). In addition, subsection (b) provides:

> **Uniformity**
>
> Such state shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

Id. § 136v(b). Since the enactment of FIFRA, the judiciary has speculated as to Congress's intent regarding the preemption of state tort claims.

B. Legislative History

Because there is no clear expression as to whether Congress intended to preempt state law tort claims by enacting FIFRA, courts often turn to FIFRA's legislative history as a guide to interpreting the provision. In 1991, this Court reviewed the legislative history of FIFRA. *Mortier*, 501 U.S. at 609-10. Before

drafting the 1972 amendment, Congress held twenty-five days of hearings and issued several committee reports. Significantly, throughout the hearings and committee reports, there is no mention of FIFRA serving to preempt state law tort claims. Because Congress was aware that consumers regularly brought state tort claims against pesticide manufacturers, it is absurd to infer that Congress intended to extinguish these ongoing causes of action without express mention in either the statutory language or the legislative history. *See Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185 (1988) (stating the court should presume that Congress is aware of the current legal landscape when it acts); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) (noting the unlikelihood that Congress would ban plaintiffs' claims without comment).

Similarly, debate surrounding the amendment's enactment indicates that Congress intended to "not affect tort liability." During the hearings, General Counsel for the EPA emphasized that states play a "major and continuing role in pesticide regulation" and that the EPA:

> wish[es] to encourage and not supplant these efforts by providing that States may prohibit the use of a particular pesticide within their jurisdiction even if the pesticide is registered under the Federal authority. States thus are not precluded from imposing stricter standards or added requirements, but they may not permit any sale or use of a pesticide which is prohibited under the authority of the Act.

Federal Pesticide Control Act of 1971: Hearings Before the House Comm. on Agric., 92nd Cong. 8 (1971). The EPA went on to state in the hearing, without objection, that FIFRA "does not affect tort liability." *Id.* at 42; *see also Federal Environmental Pesticide Control Act of 1971: Hearings Before the Subcomm. on Agric. Research of the Sen. Comm. on Agric. and Forestry*, 92nd Cong. (1972); *Federal Environmental Pesticide Control Act of 1971: Hearings Before the Subcomm. on the Envt. of the House Comm. on Commerce*, 92nd Cong. (1972); *Federal*

Environmental Pesticide Control Act of 1971: Hearings Before the Subcomm. on Agric. Research of the Sen. Comm. on Agric. and Forestry, 92nd Cong. (1971).

As noted by this Court, the Committee Reports underlying FIFRA's preemption clause are contradictory at best. *Mortier*, 501 U.S. at 609-10. On the one hand, the Senate Commerce Committee drafted a report in which an entire section was entitled, "Authority of States" indicating that the intent of the bill was "to leave to the States and local governments the authority to impose stricter regulations on pesticides [sic] use than that [sic] required under the Act." S. REP. No. 92-970, at 44 (1972), *reprinted in* 1972 U.S.S.C.A.N. 3993, 4092. The report also contained a section entitled, "Authority of Local Governments to Regulate the Use of Pesticides." *Id.* at 27. This section noted local governments should be given the authority to regulate the sale or use of a pesticide beyond the requirements imposed by state and federal authorities under the pending legislative scheme. *See id.*

On the other hand, the report of the Senate Committee on Agriculture and Forestry noted that local governments should not regulate pesticides in any manner. S. REP. No. 92-838, at 16 (1972), *reprinted in* 1972 U.S.C.C.A.N. 3993, 3993. However, the report also stated that enforcement of FIFRA would be enhanced by "authorizing cooperation with States." *Id.* This Court, in reviewing FIFRA's legislative history concluded that these two committees, which were primarily responsible for the language in FIFRA, never resolved their differences regarding the scope of FIFRA's preemption. *Mortier*, 501 U.S. at 609-10; *see also* H.R. CONF. REP. No. 92-1540, *reprinted in* 1972 U.S.C.C.A.N. 3993, 4130; S. REP. No. 92-838 (Supplemental Report) (1972); S. REP. No. 92-970 (1972), *reprinted in* 1972 U.S.C.C.A.N. 3993, 4092; H.R. REP. No. 92-511 (1971), *reprinted in* 1972 U.S.C.C.A.N. 3993.

C. Administrative Commentary

The EPA, the agency with regulatory power under FIFRA, has been outspoken as to Congress's intent regarding the scope of the preemption clause. As previously noted, the EPA issued a report in 1996 stating that courts were misinterpreting FIFRA's preemption clause. PESTICIDE REGULATION NOTICE 96-4. Most significantly, the EPA emphasized that it does not evaluate a pesticide's efficacy prior to approval. With Congress's consent, the EPA has waived inquiries into efficacy, partially because it believed that state tort law would ensure the accuracy of statements regarding a product's efficacy. That report stated,

> This notice explains EPA procedures in approving pesticide labels. . . . EPA is issuing this notice at this time to correct a misunderstanding regarding the FIFRA label approval process and efficacy claims that is reflected in a series of court decisions concerning the preemptive effect of FIFRA. . . . EPA has acted under this authority to waive, by regulation, data requirements as to efficacy issues for all agricultural pesticides [sic]. . . . [A]griculture [sic] pesticides are "effectively regulated by the marketplace," and . . . waiving review of the efficacy of agricultural pesticides in the registration process would enable the Agency to focus of [sic] its "primary mandate under FIFRA" investigating "the health and safety aspects of pesticides."

Id. The EPA went on to quote 47 Fed. Reg. 40,659, 40,661 (Sept. 15, 1982), stating that private tort-based actions ensure that pesticide manufacturers sell efficacious products and that "pesticide producers are aware that they are potentially subject to damage suits by the user community if their products prove ineffective in actual use." *Id.*

When its words went unheeded, the EPA filed an amicus brief in 2000 in a California Supreme Court case. *Etcheverry*, 993 P.2d 366. In its brief, the EPA raised the same sentiments expressed in its 1996 report and argued for a narrow

interpretation of FIFRA's preemption clause. Brief of Amicus Curiae the United States, *Etcheverry v. Tri-Ag Serv., Inc.*, 993 P.2d 846 (Cal. 2000) (No. 98-127). The EPA highlighted the original purpose of FIFRA, to protect humans and the environment and effectuate uniformity in labeling. *Id.* at 33-35. The EPA, in reviewing FIFRA's plain language and legislative intent, emphasized the lack of express language encompassing state tort claims within the preemption clause. *Id.* at 14, 19-32. Each of the seventy-five times the word "requirement" is used in FIFRA, the term refers only to positive law enactments, not tort remedies. *Id.* at 14. Because "identical words used in differing sections of a statute are presumed to have the same meaning," the EPA argued that Congress must have intended to preempt only positive law enactments and not state tort claims. *Id.* (quoting *Sullivan v. Stroop*, 496 U.S. 478, 484 (1990)); *see also Sprietsma v. Mercury Marine*, 123 S. Ct. 518 (2002).

Moreover, the EPA emphasized that FIFRA creates no private cause of action, which means that if the preemption clause encompasses tort claims, there is no remedy for those injured by a pesticide. *Id.* at 6. Thus, the EPA contended, it is unlikely that Congress intended to eviscerate pesticide-related tort claims without mention in either the text of FIFRA or its legislative history. *Id.* at 14-16. Once again, as in its 1996 report, the EPA explained that it does not evaluate a product's efficacy; it relies on state law tort claims to govern manufacturers in that area. *Id.* at 44, 19-32.

III. *This Court Should Grant Review to Reconcile the "Jurisprudential Mare's Nest" Regarding Whether FIFRA Preempts State Law Tort Claims.*

Since FIFRA's enactment in 1972, federal and state courts have manifested their confusion regarding the scope of FIFRA's preemption clause by developing a maze of contradictory case law. As federal and state courts struggled over which, if any, state law tort claims were preempted by FIFRA, this Court handed down two opinions addressing the scope of preemption clauses in other federal statutes. *See Medtronic*, 518 U.S. 470;

Cipollone, 505 U.S. 504. Despite the *Medtronic* and *Cipollone* holdings, lower courts have been unable to interpret FIFRA's preemption clause uniformly; rather, the birth of *Medtronic* and *Cipollone* only added another layer of confusion, leading to a variety of cases where courts attempted to either analogize or distinguish this Court's holdings. These varying opinions can best be organized in a chronological manner.

A. Pre-*Cipollone* FIFRA Case Law

Before this Court handed down a modern opinion about federal preemption of state law tort claims, a few courts addressed the breadth of FIFRA's preemption clause. *See, e.g., Ferebee*, 736 F.2d 1529; *Cox v. Velsicol Chem. Corp.*, 704 F. Supp. 85 (E.D. Pa. 1989); *Wilson v. Chevron Chem. Co.*, 1986 WL 14925 (S.D.N.Y. Dec. 17, 1986). First, in *Ferebee*, the Circuit Court for the District of Columbia held that FIFRA did not preempt the plaintiff's failure to warn claim against the manufacturer of a herbicide registered under FIFRA. *Ferebee*, 736 F.2d at 1530. Next, in *Wilson*, the plaintiff sought punitive damages on a failure to warn claim after her husband died from exposure to a herbicide manufactured by Chevron. *Wilson*, 1986 WL 14925 at *2. The Southern District Court of New York held that FIFRA did not preempt state law tort claims. *Id.* at *4. Thus, at least in the beginning there seemed to be some agreement that FIFRA did not preempt state law tort claims. This uniformity, however, would be greatly impacted by this Court's opinion in *Cipollone*.

B. *Cipollone v. Liggett Group, Inc.*

In 1992, this Court addressed a preemption clause in federal tobacco regulation. *Cipollone*, 505 U.S. at 515. In *Cipollone*, a smoker sued Liggett Group after becoming ill from smoking cigarettes. *Id.* at 509. Liggett argued the claim was preempted by federal tobacco regulations found in the Federal Cigarette Labeling and Advertising Act of 1965 and the Public Health Cigarette Smoking Act of 1969. *Id.* at 510. In reviewing the 1965 Act,[7]

7. "No statement relating to smoking and health, other than the statement required by . . . this Act, shall be required on any cigarette package." 15 U.S.C. § 1334(a).

this Court held that because Congress passed the Act mainly to create labeling uniformity and only intended to supersede positive enactments of state and local governments, Congress did not intend to preempt state law tort claims. *Id.* at 519. However, in reviewing the 1969 Act,[8] this Court held that the broader language indicated a congressional intent to ban all state requirements regarding advertising or promotion of cigarettes, including state common law claims if they could be said to impose such requirements. *Id.* at 523-24.

C. Post-*Cipollone* FIFRA Case Law

Many federal courts saw *Cipollone* as the answer to the confusion over FIFRA and interpreted FIFRA to be analogous to the cigarette regulations in *Cipollone.* The First Circuit interpreted FIFRA broadly and held that the plaintiffs' state law claims of negligence and strict liability were preempted because they imposed an additional "requirement" prohibited by section 136v(b). *King v. E.I. Dupont De Nemours & Co.*, 996 F.2d 1346, 1347 (1st Cir. 1993); *see also Grenier*, 96 F.3d 559 (1st Cir. 1996) (holding that claim based on inadequate labeling of log preservative used in home was preempted by FIFRA). The Seventh Circuit also relied on *Cipollone* to hold that section 136v(b) preempted state law tort claims. *Shaw v. Dow Brands, Inc.*, 994 F.2d 364 (7th Cir. 1993) (preempting plaintiff's claims of strict liability and negligence).

After this Court remanded a Tenth Circuit opinion in light of *Cipollone*, the Tenth Circuit, joined the First and Seventh Circuits in preempting state law tort claims.[9] On remand, the Tenth Circuit likened section 136v(b) to *Cipollone*'s 1969 Act and held that "[t]o the extent the state tort claims in this case

8. "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this [Act]." 15 U.S.C. § 1334(b).

9. *Ark.-Platte*, 981 F.2d at 1178. In its pre-*Cipollone* opinion, the Tenth Circuit held that failure to warn claims were impliedly preempted under FIFRA. *Id.*

require a showing that defendants' labeling and packaging should have included additional, different, or alternatively stated warnings from those required under FIFRA, they would be expressly preempted." *Ark.-Platte*, 981 F.2d at 1179. In a pre-*Cipollone* opinion, the Eleventh Circuit held the plaintiffs' claims were "impliedly preempted" after characterizing the claims of negligence, strict liability, and breach of implied warranty of merchantability claims as "inadequate labeling" claims. *Papas v. Upjohn Co.*, 926 F.2d 1019, 1026 (11th Cir. 1991), *vacated by* 505 U.S. 1215 (1992) ("*Papas I*"). This Court remanded that case in light of *Cipollone* and the Eleventh Circuit changed its holding to reflect that label-related claims were expressly preempted by FIFRA. *Papas v. Upjohn Co.*, 985 F.2d 516, 518 (11th Cir. 1993) ("*Papas II*").

The Eighth and Ninth Circuits also visited FIFRA's preemption clause after *Cipollone*, with both courts holding that tort claims are preempted by FIFRA. *See, e.g., Welchert v. Am. Cyanamid, Inc.*, 59 F.3d 69 (8th Cir. 1995) (preempting express warranty claims if based on statements required on product label); *Taylor*, 54 F.3d 555 (holding that negligent testing, breach of warranty and strict liability claims were all preempted under FIFRA); *Bice v. Leslie's Pool Mart, Inc.*, 39 F.3d 887 (8th Cir. 1994) (preempting failure to warn claims). Further, several district courts held that FIFRA preempts some, if not all, state law tort actions related to labeling. *See, e.g., Wright v. Dow Chem. U.S.A.*, 845 F. Supp. 503 (M.D. Tenn. 1993) (preempting all tort claims except defective design and failure to properly test product); *Fisher v. Chevron Chem. Co.*, 716 F. Supp. 1283 (W.D. Mo. 1989) (finding failure to warn claims preempted). Throughout this time, however, some district courts refused to find that *Cipollone* required courts to interpret section 136v(b) as broadly. *See, e.g., Burke v. Dow Chem. Co.*, 797 F. Supp. 1128, 1134-40 (E.D.N.Y. 1992) (likening FIFRA to the 1965 Act discussed in *Cipollone* and holding that FIFRA does not preempt state law tort claims).

D. *Medtronic, Inc. v. Lohr*

In 1996, this Court again visited the issue of federal preemption of state law tort claims. *Medtronic*, 518 U.S. 470. In *Medtronic*, this Court addressed the Medical Device Amendments of 1976 and whether they served to preempt a plaintiff, whose pacemaker malfunctioned, from bringing negligence and strict liability claims against the manufacturer. *Id.* at 481-84. A four-justice plurality held that Congress did not intend to encompass state law tort claims within the Act's preemption clause. *Id.* at 487-91. In distinguishing *Cipollone*, the Court held that Congress only intended to preempt those claims that conflicted with specific regulations issued by the authorized agency, the Food and Drug Administration. *Id.* at 500-01. Because the FDA had not acted in the area regarding the plaintiff's claims, the claims were not preempted. *Id.* at 501.

Thus, this Court's *Medtronic* reasoning implies that where the federal government has not issued regulations specific to the product or claim at issue, state tort claims in the unregulated area will not be preempted. *Id.* at 500. As in *Medtronic*, the use of the term "requirement" in FIFRA is not dispositive as to congressional intent to preempt state tort claims in an area of the law. *Id.* at 487. Rather, where a federal law bans additional requirements by states, the full import of such a ban must be interpreted in the relevant statutory provisions. *Id.* at 484-86.

E. Post-*Medtronic* FIFRA Case Law

Since *Medtronic*, many of the circuit courts that relied upon *Cipollone* have failed to revisit the issue of the breadth of FIFRA's preemption clause. *See, e.g., Bates*, 332 F.3d 323 (relying solely on *Cipollone*); *Lowe's Home Centers, Inc. v. Olin Corp.*, 313 F.3d 1307 (11th Cir. 2002) (same); *Nat'l Bank of Commerce, of El Dorado, Ark. v. Dow Chem. Co.*, 165 F.3d 602 (9th Cir. 1999) (citing one post-*Medtronic* case but using it for an unrelated point). However, some federal courts, along with state courts, have adjusted their holdings in light of *Medtronic* and the EPA's strenuous arguments in favor of a narrow

interpretation of the preemption clause. *See, e.g., Sleath*, 16 P.3d 1042 (adopting EPA's viewpoint that FIFRA not intended to preempt state law tort claims); *Sun Valley Packing v. Consep, Inc.*, 114 Cal. Rptr. 2d 237 (Cal. Ct. App. 2001) (relying on post-*Medtronic* case law to hold various state law tort claims unaffected by FIFRA). These cases focus on what, if any, state law tort claims are preempted and distinguish between claims based on a variety of tests and analyses. In 1999, the Third Circuit held that claims based on negligent failure to package in a manner designed to protect against decomposition of the product are not preempted by FIFRA. *Hawkins*, 184 F.3d at 255. Further, federal district courts have begun carving out exceptions to the previous holdings of their circuit courts requiring preemption of state law tort claims by FIFRA. *See, e.g., Johnson v. Monsanto Chem. Co.*, 129 F. Supp. 2d 189 (N.D.N.Y. 2001); *Jack v. Orkin Exterminating Co.*, No. 97-CV-7012 (JG), 2001 WL 25641 (E.D.N.Y. Jan. 5, 2001).

Some of the federal district courts that are bound by broad-sweeping pre-*Medtronic* precedent, hesitantly continue to find that state law tort claims are preempted by FIFRA. For instance, a California district court, bound by the Ninth Circuit's opinion in *Taylor*, preempted the plaintiff's state law tort claims. *Nathan Kimmel, Inc. v. DowElanco*, 64 F. Supp. 2d 939, 944-45 (C.D. Cal. 1999), *aff'd*, 275 F.3d 1199 (9th Cir. 2002) (affirming in relevant part and preempting all of plaintiff's claims). That court reached its holding only after openly criticizing *Taylor* and urging the Ninth Circuit to reconsider its analysis in light of *Medtronic* and the EPA's position. *Id.*

Several state courts addressing the issue have recognized that FIFRA more closely resembles the statute in *Medtronic* and, thus, does not completely preempt state law tort claims. *See, e.g., Sleath*, 16 P.3d 1042. However, state courts mirror federal courts in their struggle to interpret the breadth of FIFRA's preemption clause. *See, e.g., McAlpine v. Rhone-Poulenc Ag. Co.*; 16 P.3d 1054 (Mont. 2000) ("*McAlpine II*") (reversing the court's three year-old decision in *McAlpine v. Rhone-Poulenc*

Ag. Co., 947 P.2d 474 (Mont. 1997) ("*McAlpine I*")). For example, the Texas Supreme Court has vacillated on the issue throughout this Court's development of preemption jurisprudence. In 1995, that court held that FIFRA preempts all common law tort suits against manufacturers of EPA-registered pesticides when the claim relates directly or indirectly to labeling. *Quest Chem. Corp. v. Elam*, 898 S.W.2d 818, 820 (Tex. 1995).

After *Medtronic*, the Texas court reconsidered it position. *Geye*, 79 S.W.3d 21. In addressing the viability of the plaintiffs' crop injury claims based on strict liability, breach of express and implied warranty, and violation of the Texas Deceptive Trade Practices Act, the Supreme Court of Texas held the claims were not preempted by FIFRA. *Id.* at 29. The court, focusing on the EPA's 1996 report, held that FIFRA did not preempt all state law tort claims. The *Geye* court distinguished its previous opinion in *Quest* by stating that *Quest* "involved a claim for personal injury while [*Geye*] involved a claim for target crop damage." *Id.* The Texas court found this distinction important because the EPA has no interest in whether a pesticide is toxic to its target crop. *Id.* However, as one of its primary mandates, the EPA stringently regulates the impact pesticides have on human health. *Id.*

In one case where the EPA filed an amicus brief, the Supreme Court of California held that any claim "however couched, [that] boils down to an assertion that a pesticide's label failed to warn of the damage plaintiff allegedly suffered, the claim is preempted by FIFRA." *Etcheverry*, 993 P.2d at 377; *see also Eyl v. Ciba-Geigy Corp.*, 650 N.W.2d 744 (Neb. 2002), *cert. denied*, 123 S. Ct. 2646 (2003) (holding that bystander state tort claims for personal injury were preempted by FIFRA). *Etcheverry*, however, was not the last word regarding the breadth of FIFRA's preemption clause in California. In 2001, two California intermediate courts held that defective design, breach of express warranty, and negligence claims were not preempted

by FIFRA. *See Arnold v. Dow Chem. Co.*, 110 Cal. Rptr. 2d 722 (Cal. Ct. App. 2001); *Sun Valley*, 114 Cal. Rptr. 2d 237.

In 2000, the Supreme Court of Montana rejected California's stance on FIFRA preemption. *Sleath*, 16 P.3d 1042, *overruling McAlpine I*, 974 P.2d 474. Relying on *Medtronic* and the EPA's *Etcheverry* brief, that court overruled a previous holding and clarified that FIFRA does not preempt common law tort claims. *Id.* Other intermediate state appellate courts have also relied on *Medtronic* to distinguish federal cases and to hold that FIFRA does not preempt state law tort claims. *See, e.g., Brown v. Chas. H. Lilly Co.*, 985 P.2d 846 (Or. Ct. App. 1999); *Tyler v. Dow Chem. Co., Inc.*, 683 N.Y.S.2d 619, 620 (N.Y. App. Div. 1998).

IV. *This Court Should Grant Review to Clarify the Proper Analysis in Determining Which, if Any, State Tort Claims Are Preempted by FIFRA.*

As previously argued, federal and state judges are pitted against each other in the battle over the viability of state law tort claims in pesticide-related cases. Significantly, there exists an additional layer of conflict in the FIFRA preemption controversy. Courts that are united in holding that FIFRA preempts tort claims are splintered on the issue of the proper analysis to apply in determining which tort claims are preempted. While some courts apply a broad test, preempting all tort claims raised, others have applied more narrow tests, carving out exceptions and permitting certain claims to survive FIFRA preemption. The variety of tests applied by lower courts can be grouped into five categories: (1) Common Aims Test; (2) Efficacy Test; (3) Risk-Utility Test; (4) Label-Based Test; and (5) Inducement Test. This Court should grant review to clarify the proper analysis for determining which, if any, tort claims survive FIFRA's preemption clause.

A. The Common Aims Test

The Circuit for the District of Columbia, one of the first courts to address the issue, held that state law tort claims were not preempted by FIFRA. *Ferebee*, 736 F.2d at 1540.

The *Ferebee* opinion, which has never been revisited by the court, recognized that FIFRA's regulatory function differed from the compensatory function of state law tort claims. *Id.* Noting that potential liability promotes legitimate regulatory aims, the *Ferebee* court held that tort claims do not conflict with the language of FIFRA's preemption clause. *Id.* at 1543. The court also stated that liability for state law tort damages does not require the manufacturer to alter its label; a verdict merely informs the manufacturer that if it chooses to sell harmful pesticides in that jurisdiction, it may have to compensate for some of the resulting injuries. *Id.* at 1541. Thus, the *Ferebee* court upheld the Maryland plaintiff's claims based on inadequate labeling and established the first of the many analyses used today to determine which, if any, tort claims are preempted by FIFRA. *Id.* at 1543.

This approach is also followed in the state of Montana. *Sleath v. W. Mont Home Health Servs., Inc.*, 16 P.3d 1042 (Mont. 2000), *cert. denied*, 534 U.S. 814 (2001). In 2000, the Supreme Court of Montana handed down sister opinions in *Sleath* and *McAlpine II*, reversing the position it took "a scant three years" earlier. *Id.* at 1053 (Gray, J., *dissenting*). *Compare McAlpine II*, 16 P.3d 1054, *with McAlpine I*, 947 P.2d 474. As one basis for its abrupt about face, the Montana court relied on the EPA's anti-preemption position articulated in its amicus brief in *Etcheverry*.

Like the D.C. Circuit, the Montana Supreme Court recognized the difference between a state directly commanding that a pesticide manufacturer alter its label and a damage award that may prompt the manufacturer to make such a change. *Sleath*, 16 P.3d at 1051. Perhaps most importantly, the Montana Supreme Court scrutinized the differences between this Court's opinions in *Medtronic* and *Cipollone* and found that the analysis in *Medtronic*, leading to a finding of no congressional intent to preempt state law tort claims, applied with equal force to FIFRA. *Id.* at 1053. The state courts of Arkansas, Oregon, and New

York, along with other federal courts,[10] have adopted a similar analysis. *Alter*, 834 S.W.2d at 145; *Brown*, 985 P.2d 846; *Mann v. H.W. Anderson Prods., Inc.*, 676 N.Y.S.2d 658 (N.Y. App. Div. 1998).

Until recently, the Solicitor General of the United States supported use of this test in its amicus briefs. Briefs of Amicus Curiae the United States, *Etcheverry v. Tri-Ag Serv., Inc.*, 993 P.2d 846 (Cal. 2000) (No. 98-127) and *Hart v. Bayer Corp.*, 199 F.3d 239 (5th Cir. 2000) (No. 98-60496). In these briefs, the Solicitor General and the EPA submitted that the "courts that have concluded that FIFRA preempts state-law damages actions have done so . . . without fully examining the text, regulatory background, legislative history, and purposes of FIFRA," factors which illustrate congressional intent for state law tort actions to continue compensating for injuries caused by pesticide use. *Id.* To read FIFRA's preemption section any other way produces an absurd and unintended result — granting complete immunity to an industry Congress deemed in need of more stringent regulation. The Solicitor General and the EPA therefore urged a holding that FIFRA categorically does not preempt state law tort claims. *Id.*

However, the Solicitor General recently departed from this view. *See* Brief of Amicus Curiae the United States on Petition for a Writ of Certiorari, *Am. Cyanamid Co. v. Geye*, 79 S.W.3d 21 (Tex. 2002), *cert. denied*, 123 S. Ct. 2637 (2003) (No. 02-367). Interestingly, the EPA did not join the Solicitor General in submitting the amicus briefing in *Geye* as it had in *Etcheverry* and *Hart*. Furthermore, the EPA has not retracted PESTICIDE REGULATION NOTICE 96-4. Although it is unclear whether the lack of the EPA's imprimatur on the Solicitor General's *Geye* amicus

10. *See, e.g., Roberts v. Dow Chem. Co.*, 702 F. Supp. 195 (N.D. Ill. 1988) (following the *Ferebee* decision); *Villari v. Terminix Int'l, Inc.*, 692 F. Supp. 568, 578 (E.D. Pa. 1988) (noting "the obvious purpose underlying FIFRA's prohibition of state labeling and packaging requirements... is not undermined by the plaintiffs' failure-to-warn claim"); *Wilson*, 1986 WL 14925 (holding that liability for damages, including punitive damages, is consistent with FIFRA's purpose).

briefing suggests a divergence between the interpretation of the two offices, the fact that the Office of the Solicitor General has changed its approach between 1999 and today illustrates the widespread confusion in this area of law.

B. The Efficacy Test

Courts applying the efficacy test refuse to preempt claims related to the efficacy of a product. According to the EPA, "efficacy" is defined as either product performance (whether the product controls the target pest) or phytotoxicity (whether the product harms the target crop). Brief of Amicus Curiae the United States, *Etcheverry v. Tri-Ag Serv., Inc.*, 993 P.2d 846 (Cal. 2000) (No. 98-127). In 2002, the Supreme Court of Texas applied the efficacy test to hold that the plaintiff's claims of strict liability, breach of express and implied warranty, and violation of the Texas Deceptive Trade Practices Act were based on the efficacy of the product and, thus, not preempted by FIFRA. *Geye*, 79 S.W.3d at 27-29.

In arriving at its holding, the *Geye* court found it persuasive that the EPA requested to be relieved of its duty to regulate efficacy and Congress permitted the EPA to waive efficacy inquiries. *Id.* At 27. Thus, the EPA's waiver of efficacy regulation prompted the *Geye* court to recognize the viability of pesticide-related claims based on efficacy. *Id.* at 29 (stating "without EPA regulation, there can be no preemption"). Thus, although the common aims test and the efficacy test do allow for some state law tort claims to survive FIFRA's preemption clause, they conflict in their analyses and results. This conflict illustrates the endemic confusion surrounding the importance of the EPA's role in answering FIFRA preemption questions and underscores the need for direction from this Court.

C. The Risk-Utility Test

In an unpublished opinion, the Ninth Circuit departed from its usual FIFRA preemption analysis after receiving the answers to two questions it certified to the Washington Supreme Court. *Ruiz-Guzman v. Amvac Chem. Corp.*, No. 98-35088, 2000 WL 1763212 (9th Cir. Nov. 28, 2000). In that case, the plaintiffs

sued on a defective design theory of strict liability after becoming ill from exposure to a pesticide.[11] Under Washington law, a plaintiff may recover in strict liability under either the "consumer expectation" test or the "risk-utility" test. *Ruiz-Guzman*, 2000 WL 1763212, at *1.

On the one hand, the Ninth Circuit noted that, because FIFRA preempts label-related claims, the court was prevented from applying the consumer expectation test, which inquires into the adequacy of the product's label. *Id.* (citing *Papike v. Tambrands Inc.*, 107 F.3d 737, 743 (9th Cir. 1997) (stating, "To rule otherwise would allow the anomalous circumstance that a consumer is entitled to expect a product to perform more safely than its government-mandated warnings indicate")). Because the warnings on the pesticide at issue complied with FIFRA, the plaintiffs were unable to rely on the consumer expectation test to establish the pesticide's defective design. *Id.*

On the other hand, the Ninth Circuit held the risk-utility test, which examines whether the pesticide's utility greatly outweighs the risks posed by its use, did not conflict with the territory regulated by FIFRA. *Id.* As such, the court remanded the plaintiffs' design defect claim for application of the risk-utility test. *Id.* The Ninth Circuit's recognition that the risk-utility test may be the appropriate analysis for certain FIFRA preemption issues adds yet another varying approach to resolving this issue. The risk-utility test incorporates the existence of safer, alternative products into the equation and utilizes a cost-benefit analysis to the arena of pesticide manufacture and retailing. *Id.*; *see also* 7 U.S.C. § 136(bb) & 7 U.S.C. § 136a(d)(1)(C); RESTATEMENT (THIRD) OF TORTS § 2 cmt. f, at 24 (1998). Significant to this Court, the application of the risk-utility test to FIFRA preemption issues adds yet a fifth category of analyses

11. *Id.* at *1. Notably, due to the toxicity of the pesticide at issue and its anticipated use, the manufacturer "worked with the Washington State Department of Agriculture to develop additional restrictions on [the pesticide's] sale and use in Washington orchards." *Ruiz-Guzman v. Amvac Chem. Corp.*, 7 P.3d 795, 797 (Wash. 2000).

applied by courts across the country that are struggling to resolve the issue of FIFRA preemption. In the two decades of conflicting case law, the need for guidance from this Court has never been more evident.

D. The Label-Based Test

The "label-based test," which asks whether the plaintiff's claim can be related back to the pesticide's label, has been applied to preempt claims that a pesticide did not perform as promised,[12] "off label" warranty claims,[13] and negligence and strict liability claims alike.[14] The gravamen of this test is once "a pesticide manufacturer places EPA-approved warnings on the label and packaging of its product, its duty to warn is satisfied and the adequate warning issue ends." *Papas II*, 985 F.2d at 518; *Etcheverry*, 993 P.2d at 368. Accordingly, under this analysis, all state law tort claims that can be linked to the product's label are preempted. *Ark.-Platte*, 981 F.2d 1177. This test, or some derivative thereof, is applied by most Circuit Courts of Appeal. However, the fact that courts purport to apply the same test does not provide parties with predictable results. *Compare Hawkins*, 184 F.3d at 254 (3d Cir. 1999) (holding no preemption of defective packaging based claims), *with Lowe*, 47 F.3d at 129 (preempting defective packaging-based claims). For this reason, this area of law remains unsettled.

Conversely, should the court hold that the claim is not label-related, the plaintiff's cause of action survives. The exclusion of "off label" warranties from preemption under the label-based test is based on the principle that, "[q]uite simply, claims based on misrepresentations of fact do not challenge the labeling of a manufacturer's product." *Gorton v. Am. Cyanamid Co.*, 533 N.W.2d 746, 755 (Wis. 1995). This rule led the Supreme Court of Wisconsin to hold that misrepresentation claims related to the manufacturer's written promotional materials,

12. *See Andrus*, 178 F.3d 395.

13. *See Kuiper*, 131 F.3d 656.

14. *See Shaw*, 994 F.2d 364.

advertisements, and technical reports were not preempted. *Id.* Further, the plaintiff's claims based on oral statements made by the manufacturer's technical service representatives survived FIFRA preemption. *Id.*

However, the results of applying the label-related test are neither consistent nor predictable. For example, in 1992, the Ninth Circuit held that a state statute requiring point-of-sale warnings is not preempted, but in 1995, the same court found that failure to warn claims based on the inadequacy of point-of-sale signs were preempted. *Compare Chem. Specialties Mfrs. Ass'n v. Allenby*, 958 F.2d 941, 946-47 (9th Cir. 1992), *with Taylor*, 54 F.3d at 561. Incorporating a new layer of analysis, the Seventh Circuit held that off-label statements that repeat information contained in the label are preempted, as are claims challenging the advertising or marketing of a pesticide. *Kuiper*, 131 F.3d at 662-63.

The Fifth Circuit has applied the *Kuiper* test, but noted that other courts preempt "any claims that point-of-sale signs, consumer notices, or other informational materials failed adequately to warn the plaintiff" as such a claim "necessarily challenges the adequacy of the warnings provided on the products labeling or packaging." *Andrus*, 178 F.3d at 400. Therefore, even within the courts purporting to apply the label-based test, there is a splintering in the application process. The conflict created by such a variety of approaches undermines the concept of uniformity that Congress sought to effectuate by enacting FIFRA. The need for guidance from this Court is plainly evident.

E. The Inducement Test

Of all five categories, the inducement test is the most broad-sweeping of the tests used to interpret the scope of FIFRA's preemption clause. The inducement test focuses on the subjective inquiry of whether the tort claim would "induce" the manufacturer to change its label. *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 (5th Cir. 1994). Unlike the other tests, the inducement test encompasses claims that are objectively label-

related and expands to include those that, although not directly related to the label, may induce the manufacturer to change its label. *Andrus*, 178 F.3d at 398-99. Application of this test results in the preemption of virtually all claims arising from pesticide-related injuries. *Id.*

The Fourth Circuit applied this test to preempt claims for negligent testing, manufacture, marketing, and failure to warn. *Worm v. Am. Cyanamid Co.*, 5 F.3d 744, 747-48 (4th Cir. 1993). As evidence that liability on the plaintiffs' claims would induce the manufacturer to alter its product or label, that court emphasized that "about the same time [as the Worms filed their claim] American Cyanamid submitted to the EPA a revised label addressing the risk" complained of by the Worms. *Id.* at 746. This bolstered American Cyanamid's argument that the threat of liability would induce it to alter its label. *Id.*

In the case before this Court, the Fifth Circuit further expanded the inducement test. *Bates*, 332 F.2d 323. The Fifth Circuit ruled that the farmers' breach of warranty, fraud, DTPA, negligence, and strict liability causes of action were preempted. *Id.* at 329. However, to support its holding, the Fifth Circuit expanded upon the test originally applied by that court in *Andrus*, stating that the claims were preempted because they would have "the 'undeniable practical effect' of inducing a manufacturer to alter the **product *or* label** to avoid liability." *Id.* at 329 n.9 (emphasis added) (citing *MacDonald*, 27 F.3d at 1025).

Adoption of this altered version of the inducement test spans beyond the scope of the issues regulated by the EPA. *See* PESTICIDE REGULATION NOTICE 96-4. The EPA governs the propriety of labels, not the efficacy of the product.[15] However, the Fifth Circuit's most recent interpretation of FIFRA's preemption clause, asking whether state law tort liability would

15. As previously mentioned, the EPA defines "efficacy" as either product performance (whether the product controls the target pest) or phytotoxicity (whether the product harms the target crop). *See* Brief of Amicus Curiae the United States, *Etcheverry v. Tri-Ag Serv., Inc.*, 993 P.2d 846 (Cal. 2000) (No. 98-127).

induce the manufacturer to change the **product *or* label**, will insulate defendants from liability for the manufacture or sale of a defective product regardless of whether the labeling will be affected. *Bates*, 332 F.3d at 329. Further, it places no duty upon manufacturers to correct that defect, whether it be a flawed product or a deficient label. *Id.*

With the EPA refusing to regulate pesticide efficacy and the Fifth Circuit preempting all claims that may induce manufacturers to change their products, no agency or individual is regulating the efficacy of this nation's pesticides. *See, e.g.*, *Andrus*, 178 F.3d at 399. This grossly exaggerated *laissez faire* governance is precisely what Congress sought to avoid in enacting FIFRA and is wholly ineffective at regulating new products. Indeed, the inducement test directly contravenes the underlying motivation prompting Congress to enact FIFRA, protecting the health and environment from unsafe products. Thus, as courts continue to employ this test and insulate manufacturers from all claims, the goal of FIFRA to protect man and the environment will be rendered impotent.

Congressional intent is continually frustrated as courts continue to vary in their approach. In the states of Texas, Arkansas, Montana, Oregon, and New York, a plaintiff's claims against a manufacturer are viable in state court, but are preempted in the corresponding federal court. Thus, the conflict over the scope of the preemption clause and the proper analysis to be applied will encourage consumers and manufacturers to forum shop, seeking a venue friendly to their cause. As courts struggle to interpret FIFRA's preemption clause, there is not now nor will there ever be uniformity in the requirements of pesticide manufacturing.

V. *The Particular Disposition and Facts of This Case Present This Court with the Opportunity to Finally Resolve the Conflict Surrounding FIFRA's Preemption Clause.*

This case is distinguishable from the other FIFRA cases in which this Court has denied review. First, this case, unlike the case of *American Cyanamid Co. v. Geye*, 79 S.W.3d 21 (Tex.

2002), *cert. denied*, 123 S. Ct. 2637 (2003), contains a final disposition of the matter in controversy. Here, the Fifth Circuit finally disposed of all claims raised by the farmers by affirming the district court's grant of summary judgment giving this Court jurisdiction over the appeal.

Second, as opposed to *Netland v. Hess & Clark, Inc.*, 284 F.3d 895 (8th Cir.), *cert. denied*, 123 S. Ct. 415 (2002), this case contains claims inextricably intertwined with the two layers of conflicting case law discussed in this Petition. Most significantly, this case raises claims of crop injury, as opposed to the personal injury claim brought in *Netland*, and implicates the EPA's waiver of efficacy oversight. Permitting litigation based on crop injury claims fills the gap left open by the EPA's refusal to regulate the efficacy of pesticide-related products and encourages the production of safer pesticides. Furthermore, where *Netland* raised only one claim, failure to warn, this case includes the vast array of claims that would normally be brought in a crop injury case: breach of warranty, fraud, violations of state consumer protection laws, and strict liability based on defective design. By granting review of this case, this Court can finally resolve all issues related to the differing positions taken by federal and state courts, the EPA, and the Solicitor General regarding the scope of FIFRA's preemption clause.

Third, in this case, the Fifth Circuit ruled on each of the claims presented, holding that all claims were label-related and, therefore, preempted by FIFRA. Upon the invitation of this Court the Solicitor General of the United States filed an amicus brief advocating that this Court should not grant review because, *inter alia*, the lower court did not rule on whether the claims were label-related or imposed a "requirement" as defined by FIFRA. *See* Brief of Amicus Curiae the United States on Petition for a Writ of Certiorari, *Am. Cyanamid Co. v. Geye*, 79 S.W.3d 21 (Tex. 2002), *cert. denied*, 123 S. Ct. 2637 (2003) (No. 02-367). In the case before this Court, however, the Fifth Circuit characterized each of the claims as label-related and as

"inducing" the manufacturer to change its label or product. Thus, the questions left unanswered in *Geye* have been answered in this case.

Fourth, this case is distinguishable from all other FIFRA-related cases brought to this Court because it highlights the harm caused by the lack of uniformity in the area of FIFRA preemption. In this case, Petitioners complied with state law, giving Dow sixty days notice of their claims before filing suit. During that time, Dow used the Declaratory Judgment Act ("DJA"), codified at 28 U.S.C. § 2201, to "strike first" and secure a venue favorable to its defenses. Dow, by using the DJA expressly for purposes of forum shopping, has compounded the harm resulting from the lack of uniformity in the area of FIFRA preemption. Because conflicts of this kind give rise to a serious risk of forum shopping, they are especially deserving of this Court's attention. *Yee v. City of Escondido*, 503 U.S. 519, 538 (1992).

Both consumers and manufacturers are encouraged to forum shop based on the differing precedent of state and federal courts. For example, consumers in Texas will seek venue in state court to ensure the viability of their claims. *Geye*, 79 S.W.3d at 24. Manufacturers will seek venue in federal court, which preempts virtually all pesticide-related claims. *Bates*, 332 F.3d at 327. Absent clarification by this Court, venue will remain the dispositive factor in pesticide-related cases, encouraging all parties to forum shop.

Moreover, should consumers choose to raise a claim under a statute containing a notice provision, like the Texas DTPA, they will be required to give notice to the manufacturer prior to filing suit. It is safe to assume that Dow, along with other manufacturers, will continue to use this grace period to "strike first" and secure a venue in federal court through the offensive use of the DJA. Thus, the conflict between federal and state courts, along with the differing arguments raised by the EPA and the Solicitor General, serve as the primary motivation for

forum shopping. The requirement of notice under the laws of several states and existence of the DJA compound this problem. This Court should grant review to remove the issue of venue from the forefront of FIFRA cases, prevent forum shopping, and focus litigants' attention on the proper issue, the merits of their case.

CONCLUSION

This case raises important questions of state and federal law and the interaction between the two. The Fifth Circuit's preemption of the state law tort claims raised in this case conflicts with a 2002 decision of the Supreme Court of Texas that permits the same crop injury claims to survive. Conflicts like this exist between several other state courts of last resort and the pertinent Circuit Courts of Appeal, creating incongruent results based on geographical and jurisdictional happenstance. This case presents an important question of federal law that has not been, but should be, settled by this Court.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT FILED JUNE 11, 2003

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

No. 02-10908

DOW AGROSCIENCES LLC,

Plaintiff-Appellee

versus

DENNIS BATES; JIMMY BURSON; BENNY JUDAH, doing business as Clearwater Farms; TOMMY COLEMAN; RICHARD COX; ET AL.,

Defendants-Appellants

Appeal from the United States District Court
For the Northern District of Texas.

Before GARWOOD and HIGGINBOTHAM, Circuit Judges, and FELDMAN,* District Judge.

FELDMAN, District Judge:

Dow Agrosciences LLC sought a declaratory judgment against 29 Texas peanut farmers whom were threatening to

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* District Judge of the Eastern District of Louisiana, sitting by designation.

sue Dow for damages caused by a Dow-manufactured herbicide. Dow sought, among other things, a judicial declaration that the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136 (West 2002), preempts the farmers' state law claims. The district court denied the farmers' motion to dismiss for lack of subject matter jurisdiction and for failure to state a claim upon which relief can be granted, and granted Dow's motion for summary judgment, holding that FIFRA preempts the farmers' state law claims. We affirm.

I.

Strongarm is a herbicide produced and marketed by Dow to control the growth of weeds in peanuts. Strongarm is registered with the United States Environmental Protection Agency as required by FIFRA.

In the spring of 2000, many peanut farmers from west and northwest Texas bought Strongarm from local retailers. Many of these farmers contend that Strongarm stunted the growth of peanut plants, caused yellowing, inhibited peanuts from lapping or properly developing foliage, delayed maturity, reduced total peanut production, and increased the expense of harvesting future peanut crops.

The farmers sent Dow demand letters, claiming that Dow retailers had misrepresented Strongarm.[1] The letters

1. The farmers contend that the retailers failed to disclose that Strongarm damages peanut crops planted in soil with a pH level above 7.0.

threatened to sue Dow for false advertising, breach of warranty, and fraudulent trade practices under the Texas Deceptive Trade Practices Act (DTPA). *See* Tex. Bus. & Com. Code Ann. § 17.505(a) (Vernon 2002).

Dow struck first, and sued for declaratory judgment against 29 of the farmers. Dow sought a declaration that: (1) FIFRA preempts the farmers' state law claims; (2) the "Limitation of Remedies" paragraph on the Strongarm label limited the farmers' remedies to the purchase price of the product; and (3) the "Warranty Disclaimer" paragraph on the label barred any other claims based on a warranty of representation. The farmers counterclaimed against Dow for negligence, breach of implied and express warranties, fraud, fraud in the inducement, defective design, estoppel, and waiver.

II.

A. Subject Matter Jurisdiction

The farmers first contend that federal diversity jurisdiction did not exist over Dow's lawsuit because three of the farmers' claims failed to meet the $75,000 amount-in-controversy requirement. 28 U.S.C. § 1332(a) (West 2002). The issue of subject matter jurisdiction is subject to plenary review by this Court. *See Julian v. City of Houston*, 314 F.3d 721, 725 (5th Cir. 2002). As the party invoking diversity jurisdiction, Dow bears the burden of establishing the amount in controversy. *See Hartford Ins. Group v. Lou-Con Inc.*, 293 F.3d 908, 910 (5th Cir. 2002).

When the claim is one for declaratory relief, the amount in controversy is determined by "the value of the right to be protected or the extent of the injury to be prevented." *St. Paul Reinsurance Co., Ltd. v. Greenberg*, 134 F.3d 1250, 1252-53 (5th Cir. 1998). The amount claimed by the plaintiff controls "if the claim is apparently made in good faith." *Id.* at 1253 (quoting *St. Paul Mercury Indem. Co. v. Red Cab Co.*, 303 U.S. 283, 288 (1938)).

Dow's complaint for declaratory relief states that the value of each of the individual claims exceeds $75,000. But that bare allegation, by itself, does not invest a federal court with jurisdiction. *See Asociacion Nacional de Pescadores v. Dow Quimica*, 988 F.2d 559, 566 (5th Cir. 1993). We must therefore ascertain, based on "summary judgment type evidence," whether the amount in controversy requirement has been met. *St. Paul Reinsurance*, 134 F.3d at 1253.

The farmers point to the claims of Burk Denman, Richard Cox, and Frenchie Lee Wheeler. Their demand letters claim the following damages: Denman, $37,992.50; Cox, $33,227.50; and Wheeler, $18,242.50. All three, moreover, sought an additional $10,000 in attorney's fees. *See Hartford Ins.*, 293 F.3d at 912 (including "attorneys' fees, penalties, statutory damages and punitive damages" in the amount-in-controversy calculation).

The farmers' original damage requests, on their face, do not satisfy the $75,000 requirement; the farmers' actual claims, however, are substantially greater because the DTPA

permits a plaintiff to recover the costs of litigation, pre and post-judgment interest, and treble damages.[2] *See* Tex. Bus. & Com. Code Ann. § 17.50(b)(1) (Vernon 2002) (providing for an "award not more than three times the amount of damages for mental anguish and economic damages").

The three farmers' original demand letters did not include claims for punitive damages. Not only were such damages available to them under the DTPA, but they later sought such damages in their counterclaims. We agree with the district court that "additional demands for attorneys' fees and punitive damages exalts the total amount in controversy over $75,000."[3] Thus, federal diversity jurisdiction existed over Dow's lawsuit.

B. Abstention

Appellants next urge that the district court should have abstained from taking jurisdiction over Dow's lawsuit.

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2. The DTPA, however, does not permit the value of attorneys' fees, costs, and prejudgment interest to be included in the treble damages calculation. *See* Tex. Bus. & Com. Code Ann. § 17.50(e) (Vernon 2002).

3. The mere availability of treble damages establishes that Denman's and Cox's claims satisfy the $75,000 requirement. After trebling Wheeler's request of $18,242.50, and adding his claim for attorneys' fees, Wheeler's potential recovery is only $64,727.50. After an independent review of the record, this panel agrees with the district court that Wheeler's stated claim of $18,242.50 did not include his claim for future damages. After future damages are added to the amount of his original claim, Wheeler's total claim meets the $75,000 requirement for federal diversity jurisdiction.

District courts have a broad, but not unfettered, measure of discretion in deciding whether to entertain an action for a declaratory judgment. *See Travelers Ins. v. Louisiana Farm Bureau Federation, Inc.*, 996 F.2d 774, 778 (5th Cir. 1993); *Torch, Inc. v. LeBlanc*, 947 F.2d 193, 194 (5th Cir. 1991). Thus, a grant of declaratory relief is reviewed for abuse of discretion. *See Magnolia Marine Transport v. Laplace Towing Corp.*, 964 F.2d 1571, 1581 (5th Cir. 1992).

While acknowledging the district court's broad discretion to exercise jurisdiction over declaratory judgment suits, this Circuit requires courts to consider various factors, on the record, before abstaining from a declaratory judgment action:

> 1) whether there is a pending state action in which all the matters in controversy may be fully litigated, 2) whether the plaintiff filed suit in anticipation of a lawsuit filed by the defendant, 3) whether the plaintiff engaged in forum shopping in bringing the suit, 4) whether possible inequities in allowing the declaratory plaintiff to gain precedence in time or to change forums exist, 5) whether the federal court is a convenient forum for the parties and witnesses, . . . 6) whether retaining the lawsuit in federal court would serve the purposes of judicial economy, . . . [and] 7) whether the federal court is being called on to construe a state judicial decree involving the same parties and entered by the court before whom parallel state suit between the same parties is pending.

St. Paul Ins. Co. v. Trejo, 39 F.3d 585, 590-91 (5th Cir. 1994).

The district court correctly considered the *Trejo* factors on the record before opting to entertain Dow's declaratory action. Appellants, however, assert that the *Trejo* analysis favors abstention because Dow's lawsuit fails to implicate the core purposes of the Declaratory Judgment Act. They mistakenly rely primarily on our decision in *Magnolia Marine*. 964 F.2d 1571.

In *Magnolia Marine*, which preceded *Trejo*, our Court reversed the district court's decision to accept a declaratory judgment action. *Id.* at 1581. We mandated abstention because the declaratory suit was filed immediately after the defendant conveyed her intent to sue the plaintiffs in state court, and, we said, the plaintiffs initiated the lawsuit "solely to obtain their preferred forum in which to anticipate a defense that they could adequately raise" in state court. *Id.* at 1581-82.

Dow's first strike seems somewhat similar to the conduct in *Magnolia Marine*. Dow, too, filed for declaratory relief in anticipation of being sued in state court. Dow engaged in at least some degree of forum shopping.[4]

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4. Although Dow chose to lay venue in Lubbock, a place convenient for the farmers, the choice of a federal court was no doubt a strategic one. *See American Cyanamid Co. v. Geye*, 79 S.W.3d 21, 23 (Tex. 2002).

Against the measure of *Magnolia Marine*, the first three *Trejo* factors appear to favor abstention.[5] We nonetheless agree with the district court that the last three factors clearly instruct against abstention: the resolution of this dispute in a single federal forum furthers the interests of judicial economy;[6] the federal forum does not appear to be inconvenient to the farmers; and the federal court was not asked to construe a state judicial decree involving the same parties as those involved in a parallel, pending state suit.[7] *See Trejo*, 39 F.3d at 590-91.

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5. We assume, *arguendo*, that the first *Trejo* factor supports abstention despite the fact that the federal suit was filed first. Pursuant to the statutory notice requirements of the DTPA, the farmers were precluded from bringing a state court action at any time within sixty days from the date the demand letters were mailed, and Dow brought its declaratory judgment action after the farmers had taken the requisite first steps toward bringing a DTPA action.

6. In *Cunningham Brothers, Inc. v. Bail*, 407 F.2d 1165 (7th Cir. 1969), the Seventh Circuit disregarded the fact that federal court abstention would force the defendant to defend lawsuits in various jurisdictions against a variety of plaintiffs. *Id.* at 1168-69. The *Cunningham* panel, however, emphasized repeatedly that the underlying action was one of personal injury. Because the scope of *Cunningham* appears limited to personal injury actions, and is not a ruling of this Circuit, we find it to be of little persuasion. We find that resolving the farmers' claims in a single federal forum clearly furthers the interests of judicial economy.

7. It is unclear from the record whether the fourth factor, concerned with inequities gained by a plaintiff's precedence in time, supports abstention.

Thus, "[i]n light of the breadth of the district court's discretion," *Torch*, 947 F.2d at 195, and because the weight of the *Trejo* factors appears to be balanced and to have been properly considered by the district court on the record, we find that the court did not abuse its discretion by entertaining Dow's suit for declaratory judgment.

C. FIFRA Preemption

Appellants also contend that the district court erred when it decided, by way of summary judgment, that FIFRA preempted their state law claims. Our review of a district court's grant of summary judgment is *de novo*. *See Young v. Equifax Credit Information Services, Inc.*, 294 F.3d 631, 635 (5th Cir. 2002).

Preemption analysis proceeds from "the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 605 (1991). Preemption may nonetheless occur in one of three ways: it may be expressed by the federal statute, it may be implied from the terms or structure of a federal statute, or it may arise in a situation where a conflict between state and federal regulations makes compliance with both a physical impossibility. *See id.* The district court found that FIFRA expressly preempted the farmers' state law claims. We agree.

FIFRA is a comprehensive regulatory scheme aimed at controlling the use, sale, and labeling of pesticides. *See id.* at 601. FIFRA requires, among other things, that manu-

facturers submit proposed product labels for EPA approval. *See* 7 U.S.C. § 136a(c)(1)(C) (West 2002).

Section 136v of FIFRA announces:

> (a) In General
>
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.
>
> (b) Uniformity
>
> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

The Court has addressed the scope of § 136v(b) many times. *See Hart v. Bayer Corp.*, 199 F.3d 239 (5th Cir. 2000); *Andrus v. Agrevo USA Co.*, 178 F.3d 395 (5th Cir. 1999); *MacDonald v. Monsanto*, 27 F.3d 1021 (5th Cir. 1994). Our decisions reveal three clear principles. First, FIFRA does not completely preempt all state or local regulation of pesticides. *See Hart*, 199 F.3d at 244 (rejecting an attempt to premise federal question jurisdiction on a claim of complete preemption). Second, FIFRA does not preempt common law that is unconcerned with herbicide labeling, nor does it preempt those state laws concerned with herbicide labeling that do not impose any requirement in addition to or different

from the FIFRA requirements.[8] *See Andrus*, 178 F.3d at 398; *see also Hart*, 199 F.3d at 245 ("FIFRA preemption does not extend to non-labeling state common-law causes of action."). Finally, FIFRA preempts state laws that either directly or indirectly impose different labeling requirements.[9] *See MacDonald*, 27 F.3d at 1025.

The district court found that each of the farmers' state claims were preempted under § 136v(b) because they constituted "requirements for labeling and packaging in addition to those required under" FIFRA.[10] Appellants advance two arguments against preemption. First, they contend that state labeling requirements related to product effectiveness are not within the scope of FIFRA's express preemption clause. Second, they assert that their claims are not sufficiently related to the content of the Strongarm label. We reject each argument.

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8. It is well-established that the term "any requirements" encompasses both positive state enactments as well as common-law causes of action. *See Andrus v. Agrevo USA Co.*, 178 F.3d 395, 398 (5th Cir. 1999).

9. For example, different requirements may be imposed when a court authorizes a damage award against a manufacturer that has the "undeniable practical effect" of inducing a manufacturer to alter the product or label to avoid liability. *See MacDonald v. Monsanto*, 27 F.3d 1021, 1025 (5th Cir. 1994). It is this mandate that is fatal to appellants' argument.

10. Thus, we first review whether the farmers' claims are expressly preempted by § 136v(b); if FIFRA does not expressly preempt the farmers' claims, it becomes necessary to analyze whether such claims conflict with federal law.

1) State Labeling Requirements Related to Product Effectiveness are Within Scope of FIFRA's Express Preemption Clause

Appellants urge that their product effectiveness claims, even those which impose a labeling requirement, are not within the scope of FIFRA's express preemption clause. Their argument suggests that FIFRA preemption of performance-related claims requires the existence of conflicting EPA enactments.

In *Cipollone v. Liggett Group, Inc.*, the Supreme Court held that, as long as a federal statute[11] contains an express preemption clause, it is wholly unnecessary and inappropriate to import notions of implied preemption through conflict into the express preemption analysis.[12] 505 U.S. 504, 517, 531-

11. *Cipollone* reviewed the express preemption clause in the Public Health Cigarette Smoking Act of 1969. The Smoking Act of 1969 and FIFRA are strikingly similar. The Tenth Circuit has written, "Although the words employed in § 136v(b) are different from those in § 5(b) of the Cigarette Smoking Act, their effect is the same . . . [and w]e see no difference between the operative effect of the two acts." *Arkansas-Platte & Gulf v. Van Waters & Rogers*, 981 F.2d 1177, 1179 (10th Cir. 1993). Moreover, the Seventh Circuit also "discern[ed] no significant distinction at all" between the two clauses. *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 371 (7th Cir. 1993) ("Not even the most dedicated hair splitter could distinguish these statements.").

12. "Where, as here, Congress has included in legislation a specific provision addressing . . . pre-emption, the Court's task is one of statutory interpretation—only to identify the domain expressly

(Cont'd)

32, 544, (1992)(plurality opinion). Nowhere in FIFRA's text is § 136v(b)'s express preemptive command, or § 136v(a)'s savings clause, linked to the interplay of EPA regulations. 7 U.S.C. § 136 (West 2002); *see also Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers*, 981 F.2d 1177 (10th Cir. 1993)("We believe Congress circumscribed the area of labeling and packaging and preserved it only for federal law . . . [w]ith the same stroke, Congress banned *any* form of state regulation, and the interdiction law is clear and irrefutable.") (emphasis added).

Although FIFRA's text does not define the scope of FIFRA's preemption clause to be a function of existing EPA regulations, appellants nonetheless insist that an implied conflict preemption analysis must be imported into § 136v(b). To support their claim, they rely primarily on the Texas Supreme Court's decision in *American Cyanamid Co. v. Geye*, which held that the EPA's decision to not regulate product labeling "with respect to how well a product works" meant that "state common-law claims about target area crop damage are not preempted." 79 S.W.3d 21, 23 (Tex. 2002). The Texas

(Cont'd)

pre-empted by the provision. An interpreting court must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose. We resort to principles of implied preemption—that is, inquiring whether Congress has occupied a particular field with the intent to supplant state law or whether state law actually conflicts with federal law—only when Congress has been silent with respect to pre-emption." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 532 (Blackmun, J., concurring in part and dissenting in part) (internal quotations omitted).

high court reasoned, "EPA regulations define the domain expressly preempted" by FIFRA because Congress gave the EPA the "role of evaluating and determining the content of pesticide labels." *Id.* at 24 (citing 7 U.S.C. 136w(a)(1) (West 2002)) (internal quotation omitted).

We find *Geye* unhelpful because it did not address the principal issue: whether the scope of FIFRA's express preemption clause includes product effectiveness claims which relate to product labeling. *Geye* holds only that the specific Texas state-law claims for crop damage did not present a problem of conflict preemption under the applicable EPA regulations. In other words, *Geye* proceeds from the assumption that the claims at issue did not relate to product labeling and that FIFRA's express preemption clause did not apply.[13]

The scope of FIFRA's express preemption clause is defined by the simple text of § 136v. That the EPA has not elected to impose labeling regulations concerning product

13. That *Geye* is properly understood as an ordinary conflict-preemption case is evident from two portions of the opinion. First, in the opening paragraphs of its opinion, the Texas court references only the "exception to preemption" clause of FIFRA. *American Cyanamid Co. v. Geye*, 79 S.W.3d 21, 22 (Tex. 2002). By the "exception to preemption" clause, the court was clearly referring to § 136v(a), not to the express preemption clause of § 136v(b). Second, it is also apparent from Part V of its opinion, in which the court appeared to conclude that the underlying claim alleged to be preempted was not a claim "relating directly or indirectly to labeling," *see* 79 S.W.3d at 29 (distinguishing *Quest Chemical Corp. v. Elam*, 898 S.W.2d 819 (Tex. 1995)), that the court's opinion did not purport to interpret section 136v(b).

effectiveness does not alter the plain meaning of § 136v(b) nor avoid preemption of a claim that has the effect of imposing labeling requirements. For a state to create a labeling requirement by authorizing a claim linked to the specifications of a label, even where the EPA has elected not to impose such labeling requirements, would clearly be to impose a requirement "in addition to or different from those" required under FIFRA. *See* 7 U.S.C. § 136v(b). Thus, the farmers' claims, including those which challenge Strongarm's effectiveness, are within the scope of FIFRA's express preemption clause if they are related to the content of the Strongarm label.

2) The Farmers' Claims are Sufficiently Related to the Content of Strongarm Label

The farmers argue that their claims are not related to the Strongarm label. This argument betrays the facts and it betrays common sense. We have observed that FIFRA's express preemption clause is self-executing. Thus, the farmers' claims are expressly preempted under § 136v(b) if a judgment against Dow would induce it to alter its product label. *See Andrus*, 178 F.3d 395, 399 (5th Cir. 1999) (finding that state law claims that herbicide had "failed to perform as specified pursuant to the label" were preempted by FIFRA because the plaintiff's success on such claims would necessarily have had the effect of "imposing additional labeling standards").

The facts aside for one moment, a claim's relatedness to a product label may be determined simply by reference to the party's pleadings. *See id.*, at 399. Unlike *Andrus*, where

the plaintiff's complaint specifically referenced "specifications set forth in the label," the farmers' counterclaim simply asserts in general that the label did not include a valid disclaimer or limitation of remedies. We, therefore, look at each of the farmers' state claims[14] to determine whether a judgment against Dow would cause it to need to alter the Strongarm label. *See MacDonald*, 27 F.3d at 1024 ("[C]ourts must compare the particular language of a statute's preemption provision with each common law claim asserted to determine whether the common law claim is in fact preempted.").

a) Breach of Warranty, Fraud and DTPA

The farmers base their breach of warranty, fraud, and DTPA claims on misleading comments made by Dow retailers. Claims for breach of warranty based upon an "off label" representation are preempted by FIFRA only if the representation deviates from the contents of the product label. *See Andrus*, 178 F.3d at 399. Success on such an "off label" claim would provide a manufacturer with a strong incentive to alter its label to avoid future liability. *See id.*

The district court found that the farmers failed to establish a genuine issue of material fact that the Dow retailers' comments differed or strayed in any material manner

14. Although the farmers asserted breach of contract in their counterclaim, they failed to address this issue in their brief. Thus, any objection related to the district court's finding of preemption regarding breach of contract is waived. *See Oden v. Oktibbeha County, Miss.*, 246 F.3d 458, 470 n.12 (5th Cir. 2001).

from the contents of the Strongarm label.[15] After reviewing the record, we agree with the district court. Thus, the farmers' warranty claims are preempted under § 136v(b). *See id.* at 400 (refusing to overturn a grant of summary judgment on a defense of preemption where the plaintiffs failed to establish that the representations forming the basis of the claim differed from the contents of the FIFRA label).

The farmers' fraud claims, based upon the same "off label" statements by Dow representatives, are subject to an identical analysis. Because no evidence was presented demonstrating that the retailer statements deviated from the contents of the Strongarm label, the fraud claims are similarly preempted by § 136v(b).

The DTPA does not create a warranty; rather, it establishes a remedy for the breach of an independent warranty. *See Centex Homes v. Buecher*, 95 S.W.3d 266, 269 (Tex.2002). Because the only warranty at issue is based upon these "off-label" comments, the farmers' success on a DTPA action would also induce Dow to alter its label. The DTPA claim is thus necessarily preempted by FIFRA § 136v(b).

15. The district court held that one pre-sale representation by Dow retailers deviated from the content of the Strongarm label. The court found that the representation, however, was controlled by the label's "Limitation of Remedies" provision. The farmers' do not seek appellate review of the district court's application of the "limitation of remedies" provision.

b) Defective Design

Defectively manufactured or designed products properly labeled under FIFRA are generally subject to state regulation. *See Netland v. Hess & Clark, Inc.*, 284 F.3d 895, 899 (8th Cir. 2002). Dow, however, correctly contends that the farmers' defective design claim is merely a disguised claim for failure to warn. *See Grenier v. Vermont Log Buildings, Inc.*, 96 F.3d 559, 564 (1st Cir. 1996) ("[M]erely to call something a design or manufacturing defect claim does not automatically avoid FIFRA's explicit preemption clause."). One cannot escape the heart of the farmers' grievance: Strongarm is dangerous to peanut crops in soil with a pH level over 7.0, and that was not disclosed to them.

In *Netland*, the Eighth Circuit evaluated a FIFRA preemption defense to a strict liability claim. *See Netland*, 284 F.3d at 899. The *Netland* court found that the plaintiff's expert testimony was insufficient to establish a design defect, and that the claim was obviously more directed to deficiencies in the EPA-approved label. *See id.* at 900-01.

Netland is a good guide for us. The farmers' counterclaim presents a straightforward design defect claim, that Strongarm was unreasonably dangerous at the time it left Dow's control. Nonetheless, the farmers did not claim that Strongarm is unreasonably dangerous for use on all peanut crops; rather, they asserted that Strongarm is dangerous when applied to crops in soil with high pH levels. *See Grenier*, 96 F.3d at 565 (finding plaintiff's claim that a product was defectively designed because it was foreseeable that it would be used in

a particular way "is effectively no more than an attack on the failure to warn against [that] use and therefore is a preempted claim").

We find that the farmers' strict liability counterclaim is functionally a disguised claim for failure to warn. It is inescapable that success on this claim would again necessarily induce Dow to alter the Strongarm label. The district court did not err in ruling that FIFRA expressly preempts the farmers' defective design claim.

c) Negligence

The farmers also maintain that Dow was negligent in the testing, manufacture, and production of Strongarm. They overlook that a negligent testing claim is, as a matter of Texas law, a variation of an action for failure to warn. *See American Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 437 (Tex. 1997). We agree with the district court that the farmers' negligent manufacture claim was, again, simply a disguised claim for failure to warn and is preempted by § 136v(b).

III.

Each of the farmers' claims exceeded the $75,000 statutory requirement for federal diversity jurisdiction. Moreover, the district court conducted a proper *Trejo* abstention analysis. Given that the balance of the *Trejo* factors does not appear to point clearly toward abstention, we find that the district court did not abuse its discretion by entertaining the declaratory judgment action. We reiterate that, because FIFRA's express preemption clause is self-executing,

Appendix A

FIFRA preemption of performance-related state law claims is not dependent upon the existence of conflicting EPA regulations. Moreover, the farmers' claims for breach of warranty, fraud, DTPA, defective design and negligence are all preempted by FIFRA's express preemption clause because success on such claims would necessarily induce Dow to alter its product label. AFFIRMED.

APPENDIX B — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS, LUBBOCK DIVISION DATED AND FILED JUNE 3, 2002

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

Civil Action No. 5:01-CV-331-C

DOW AGROSCIENCES, LLC,

Plaintiff,

v.

DENNIS BATES, et al.,

Defendants.

ORDER

On this day the Court considered Plaintiff's Motion for Summary Judgment filed March 13, 2002. Defendants filed a Response to Plaintiff's Motion to Dismiss on April 2, 2002. Plaintiff filed a Reply on April 19, 2002. After considering all relevant arguments and evidence, the Court **GRANTS** Plaintiff's Motion for Summary Judgment.

Appendix B

I.

BACKGROUND

Plaintiff, Dow AgroSciences, manufactures pest management and biotechnology products. Plaintiff introduced Strongarm in the spring of 2000. Strongarm is used as a preemergence herbicide to control certain weeds in peanuts. Plaintiff began receiving demand letters from individual peanut growers (Defendants) contending that Strongarm was "highly toxic" and failed to control the weeds in their peanut crops. The Defendants also contended that Plaintiff misrepresented the product and that the misrepresentations constituted false, misleading, and deceptive acts and practices. In addition, Defendants alleged false advertising, breach of warranty, and statutory claims for alleged deceptive and fraudulent trade practices. Defendants' demand letters demanded payment from Plaintiff for certain damages, including consequential and incidental damages, treble damages, and attorneys' fees and expenses. On December 21, 2001, Plaintiff brought suit seeking declaratory judgment.

II.

STANDARD

Summary judgment is appropriate only if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any," when viewed in the light most favorable to the non-moving party, "show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." *Anderson v.*

Appendix B

Liberty Lobby, Inc., 477 U.S. 242, 247 (1986) (internal quotations omitted). A dispute about a material fact is "genuine" if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Id.* at 248. In making its determination, the court must draw all justifiable inferences in favor of the non-moving party. *Id.* at 255. Once the moving party has initially shown "that there is an absence of evidence to support the nonmoving party's case," *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986), the non-movant must come forward, after adequate time for discovery, with significant probative evidence showing a triable issue of fact. Fed.R.Civ.P. 56(e); *State Farm Life Ins. Co. v. Gutterman*, 896 F.2d 116, 118 (5th Cir. 1990). Conclusory allegations and denials, speculation, improbable inferences, unsubstantiated assertions, and legalistic argumentation are not adequate substitutes for specific facts showing that there is a genuine issue for trial. *Douglass v. United Servs. Auto. Ass'n*, 79 F.3d 1415, 1428 (5th Cir. 1996) (en banc); *SEC v. Recile*, 10 F.3d 1093, 1097 (5th Cir. 1993). To defeat a properly supported motion for summary judgment, the non-movant must present more than a mere scintilla of evidence. *See Anderson*, 477 U.S. at 251. Rather, the non-movant must present sufficient evidence upon which a jury could reasonably find in the non-movant's favor. *Id.*

III.

DISCUSSION

Plaintiff filed this suit in an effort to have the Court determine the parties' rights and obligations under the applicable federal law. Plaintiff contends that the Federal

Insecticide, Fungicide and Rodenticide Act ("FIFRA") expressly preempts all of Defendants' claims against Plaintiff. Defendants assert that their claims are not expressly preempted by FIFRA.

FIFRA creates a comprehensive regulatory scheme for pesticide and herbicide labeling. *See Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 601 (1991). Under its provisions, all herbicides sold in the United States must be registered with the Environmental Protection Agency ("EPA"). *See* 7 U.S.C. § 136a(a). FIFRA also establishes a complex process of EPA review that culminates in the approval of the label under which the product is marketed. *See* 7 U.S.C. § 136a(c). A pesticide manufacturer must submit a "statement of all claims to be made for" the herbicide as well as directions for its use, its ingredients, and its adverse effects. *See* 7 U.S.C. § 136a(a). The EPA then registers the herbicide if it determines that its composition is such as to warrant the proposed claims for it, that its labeling complies with FIFRA requirements, and that it will perform its intended function without unreasonable adverse effects on the environment. *See* 7 U.S.C. § 136a(c)(5). In an effort to preserve uniformity of laws concerning labeling, FIFRA provides that states "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under" FIFRA. *See* 7 U.S.C. § 136v(b). Section 136v(b) preempts those state laws that impose or effect different or additional labeling requirements. *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 (5th Cir. 1994) The express language of FIFRA clearly indicates that Congress intended that the federal act preempt

conflicting state law, including state common law tort claims. *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 (5th Cir. 1994).

Plaintiff's first assertion is that FIFRA expressly preempts Defendants' alleged breach of implied warranty claims. Defendants on the other hand claim that FIFRA does not preempt their implied warranty claims because these claims are not based on inadequacies in labeling. Defendants claim that the alleged breach of implied warranty claims arise from field day projects sponsored by Plaintiff. Defendants allege that at the field day projects, they were told that Strongarm was an excellent herbicide to use for weed control on West Texas Peanuts. The Court finds that FIFRA preempts Defendants' breach of implied warranty claims because "[i]n every instance the defects alleged [by Defendants] are linked to the specifications set forth in the label." *Andrus v. Agrevo USA Co.*, 178 F.3d 395, 399 (5th Cir. 1999). Defendants attempt to avoid FIFRA preemption because they "challenge misrepresentations that were made separately from the label." *See Andrus*, 178 F.3d 395, 400 (quoting *Kuiper v. American Cyanamid Co.*, 131 F.3d 656, 662 (7th Cir. 1997)). Defendants' argument fails as Defendants have failed to raise a genuine issue of material fact suggesting that the advice and statements made at the field day projects differed from the contents of the Strongarm product label. The implied warranty claims are preempted by FIFRA because they challenge the Strongarm label.

Plaintiff also asserts that FIFRA preempts Defendants' alleged breach of express warranty claims. Defendants claim that because express warranties are not a requirement

imposed by a state, they are not preempted under FIFRA. However, premising liability on the inaccuracy of a statement on the label is in effect challenging the label, and FIFRA preempts any claim that directly or indirectly challenges the sufficiency of the label. The express warranty claims are preempted by FIFRA because they challenge the Strongarm label.

Additionally, Plaintiff claims that Defendants' alleged breach of implied and express warranty claims are foreclosed by Strongarm's label provisions. Strongarm's label provisions specifically disclaim any implied warranties and provide a limited express warranty.[1] In Texas, the UCC provides for the exclusion or modification of warranties. Tex. Bus. & Com. Code Ann. § 2.316(b) (Vernon 2000). Section 2.316(b) provides as follows:

> (b) Subject to subsection (c), to exclude or modify the implied warranty of merchantability or any part of it the language must mention merchantability and in case of a writing it must be conspicuous, and to exclude or modify any implied warranty of fitness the exclusion must be writing and conspicuous. Language to exclude all

1. Strongarm's label provides as follows: "Dow AgroSciences warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in strict accordance with the directions, subject to the inherent risks set forth below". Dow AgroSciences MAKES NO OTHER EXPRESS OF IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

> implied warranties of fitness is sufficient if it states, for example "there are no warranties which extend beyond the description on the face hereof".

Whether a disclaimer is conspicuous or not is a question of law. Section 1.201(10) of the Texas Business and Commerce Code states that "a term or clause is conspicuous when it is so written that a reasonable person against whom it is to operate ought to have noticed it. A printed heading in capitals is conspicuous." Tex Bus. & Com. Code Ann. § 1.201(10) (Vernon Supp. 2002). Strongarm's label provision excluding any express or implied warranty meets the letter of the Texas UCC and thus is enforceable. Tex Bus. & Com. Code Ann. § 2.316(b); 2.316(b), (c) (Vernon 2000). Assuming *arguendo* that Defendants' claims for an alleged breach of express and implied warranties were not preempted by FIFRA, the claims would be foreclosed by Strongarm's label provisions. Plaintiff's Motion for Summary Judgment on Defendants' breach of implied and express warranty claims is **GRANTED.**

Plaintiff contends that Defendants' Deceptive Trade Practices Act and Fraud claims are preempted by FIFRA because these claims ultimately challenge the Strongarm label. Plaintiff claims that Defendants' DTPA and fraud claims are in essence misrepresentation through advertising claims which are challenges to the Strongarm label. Defendants deny that their DTPA and fraud claims are predicated solely on advertisements. Defendants assert that their claims arise from the representations made by Plaintiff's retail distributors and employees who conducted the field day projects and who instructed Defendants about the uses

of Strongarm and from promotional advertising by Plaintiff. Defendants claim that their DTPA and fraud claims are based on the representations and promises made by Plaintiff's authorized local retail distributors and representatives.

Controlling Fifth Circuit law establishes that FIFRA preempts claims that rely on advertising and marketing materials as the basis for their DTPA and fraud claims. *Andrus*, 178 F.3d at 400. Specifically, the Fifth Circuit has held that FIFRA preemption cannot be avoided "simply because [he] challenge[s] alleged misrepresentations that were made separately from the label." *Andrus*, 178 F.3d at 400 (citing *Kuiper v. American Cyanamid Co.*, 131 F.3d 656, 662 (7th Cir. 1997)). Defendants state that their claims arise from representations made by Plaintiff's retail distributors and employee representatives who conducted field day projects and "held meetings with the Defendant growers instructing them about the uses of Strongarm, how to apply it, extolling its excellent results in west Texas soils with west Texas weeds and from promotional advertising" by Plaintiff. Defendant has offered no evidence that these "off-label" remarks were different from the information contained in the Strongarm label. *See Andrus*, 178 F.3d at 400 (citing *Kuiper*, 131 F.3d at 662-63). Off-label remarks are preempted when they merely repeat the information on the label. *See id.* These remarks Defendants complain of merely repeat the information contained on the Strongarm label; therefore, FIFRA preempts these claims.

Defendants also complain about statements made by Plaintiff's employee representatives who examined the Defendants' fields and advised them that the peanuts would

grow out of the problem and that Plaintiff would pay the growers for any production loss and increased expenses. These off-label remarks do not repeat any information found on the Strongarm label. FIFRA does not preempt these claims. However, the Strongarm label contained a Limitation of Remedies provision. The provision provides as follows:

"The exclusive remedy for losses or damages resulting from the use of this product (including claims based on contract, negligence, strict liability, or other legal theories) shall be limited to, at Dow AgroSciences' election, one of the following:

1. refund of purchase price paid by buyer or user for product bought, or

2. replacement of amount of product used."

Dow AgroSciences shall not be liable for losses or damages resulting from handling or use of this product unless Dow AgroSciences is promptly notified of such loss or damage in writing. In no case shall Dow AgroSciences be liable for consequential or incidental damages or losses.

The Terms of the Warranty Disclaimer above and this Limitation of Remedies cannot be varied by any written or verbal statements or agreements. "No employee or sales agent of Dow AgroSciences or the sell is authorized to vary or exceed the terms of the Warranty Disclaimer or this Limitation of Remedies in any manner."

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Section 2.719 of the Texas Uniform Commercial Code provides that parties can limit their liability in damages. Tex Bus. & Com. Code Ann. § 2.719. The Limitation of Remedies on the Strongarm label complies with the Texas UCC. As such, the alleged statements made by the Plaintiff's employees and representatives do not vary the terms of the Limitation of Remedies. Defendants are limited to the remedies provided in the Limitation of Remedy provision.

Plaintiff's final assertion is that Defendants' negligence claims are preempted by FIFRA. Defendants argue that Plaintiff was "negligent in the development, manufacture, production and promotion of Strongarm." In support of their argument, Defendants claim that the affidavit of John M. Brown, Ph.D. demonstrates that Plaintiff was negligent in the design, formulation, manufacture, and promotion of Strongarm in west Texas. In addition, Defendants claim that the fact that Plaintiff changed the Strongarm label for the 2001 peanut season supports their assertion that Plaintiff was negligent in the design, formulation, manufacture, and promotion of Strongarm. Defendants further state that had the 2001 label changes been made in 2000, "the growers would not have used Strongarm and would not have suffered the injuries to their crops that they did." In effect, the Defendants are challenging the Strongarm label. The Defendants' negligence claim is in actuality a failure to warn claim that is preempted. *Cipolone v. Liggett Group*, 505 U.S. 504, 524 (1992). Plaintiff's Motion for Summary Judgement on this point is **GRANTED.**

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IV.

CONCLUSION

For the reasons previously discussed, Plaintiff's Motion for Summary Judgment is **GRANTED.** All other pending motions are DENIED as MOOT. All relief not expressly granted is **DENIED.**

SO ORDERED.

Dated this 3rd day of June, 2002.

s/ Sam R. Cummings
SAM R. CUMMINGS
UNITED STATES DISTRICT JUDGE

NOV 13 2003

No. 03-388

IN THE

Supreme Court of the United States

DENNIS BATES; JIMMY BURSON; BENNY JUDAH, doing business as CLEARWATER FARMS; TOMMY COLEMAN; RICHARD COX; WAYNE DAVIS; NEIL FRIESSEN; JAKE FORESE; THOMAS FUSTON; ARTHUR GALVAN, doing business as G-5 PARTNERSHIP; GREG HUGHES; SANDRA and KARL DON HUGHES, doing business as JH CATTLE CO.; RUDY KLASSEN; RONNIE LOVE; KEVIN MATHIS; BRAD PALMER; KIRK PARRISH, doing business as K-L FARMS; JERRY PARRISH; JoEVELYN PATTERSON and DONALD GRUBEN; STACEY PRICE; BENNY JUDAH, doing business as PROGRESSIVE FARMS; MORRIS RUSHING, doing business as PEA-COT FARMS; BILLY SHANNON, FLOYD STOKES; CRAIG WEST; FRENCHIE LEE WHEELER,

Petitioners,

v.

DOW AGROSCIENCES LLC,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF IN OPPOSITION

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STATEMENT PURSUANT TO RULE 29.6

Dow AgroSciences LLC is a wholly owned subsidiary of The Dow Chemical Company.

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STATEMENT OF THE CASE

I. Introduction

Respondent Dow AgroSciences LLC ("Dow AgroSciences") respectfully requests that the Petition be denied because, first, there is no legitimate, meaningful split in authority over FIFRA preemption. Following *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), nine federal circuits, and the supreme courts and/or intermediate appellate courts of twenty-seven states, have all agreed that 7 U.S.C. § 136v(b) expressly preempts common law challenges to EPA-accepted pesticide product labels. In addition, one state supreme court (Texas') and one federal circuit (the Third) generally agree, but hold that FIFRA preemption depends upon factually-sensitive timing and intensity of EPA scrutiny of the data underlying the challenged aspect of a particular pesticide's label or packaging. Only one state supreme court (Montana's, over a strong dissent by its now-Chief Justice) and only one state's intermediate appellate court (Oregon's) have disagreed.[1]

Second, Petitioners' arguments for reversal here, relying upon the regulation-dependent analysis accepted in Texas and the Third Circuit, are ultimately futile. Such an exception to preemption simply does not apply to the specific facts of this case because Dow AgroSciences, in applying for the federal registration of its Strongarm herbicide, submitted a massive amount of efficacy and crop safety data to the EPA for its consideration.

Third, the Montana and Oregon decisions do not create a legitimate, meaningful conflict. Indeed, the decision by the Montana court is immediately suspect because it is premised entirely upon arguments offered in a widely-rejected and otherwise-unsuccessful government *amicus* brief that the United States Solicitor General has now expressly and categorically repudiated in a recent *amicus* brief to this Court. The decision by the Oregon court is equally suspect because it wholly misinterprets this Court's decision in *Medtronic, Inc. v.*

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1. The issue of FIFRA preemption has not reached the remaining two regional federal circuits, the District of Columbia Circuit, or the appellate courts of the remaining twenty-three states since *Cipollone*.

Lohr, 518 U.S. 470 (1996), reaching a conclusion contradicted by not less than twenty-two published FIFRA decisions directly holding that *Medtronic* does not alter the FIFRA preemption analysis.

II. Statement Of The Facts

In 1992, Dow AgroSciences began the lengthy application process for federal registration of its new diclosulam-based herbicide, later named Strongarm. As required by the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y, and its implementing regulations, Dow AgroSciences submitted massive amounts of product data to the United States Environmental Protection Agency ("EPA") in support of its application.

Because Strongarm's application for registration was submitted under the 1996 amendments to FIFRA, specifically 7 U.S.C. § 136a(c)(10) (authorizing the Reduced Risk Initiative implemented by the EPA through PESTICIDE REGULATION NOTICE 97-3 (Sept. 4, 1997)), Dow AgroSciences submitted a comprehensive body of data on Strongarm's efficacy in controlling broadleaf weeds in peanuts and its safety for that use. The EPA's final rule authorizing registration of diclosulam, Strongarm's active ingredient, proves that the EPA required and considered such data for Strongarm: "The petitioner has proposed the following plantback restrictions . . . 9 months for . . . *peanuts* . . . *due to phytotoxicity*." 65 Fed. Reg. 12129, 12133 (March 8, 2000) (emphasis added). The EPA's consideration of soil pH factors as influencing crop safety specifically is proven by the EPA's approval of this warning for Strongarm's label:

> ***Note:*** *Environmental and soil factors can influence the performance and selectivity of any herbicide treatment. . . . factors such as pH. . . can contribute to reduced crop tolerance to a soil-applied herbicide.*

(italics original, emphasis added).

Strongarm's federal registration ultimately issued on March 8, 2000, pursuant to 7 U.S.C. § 136a(c)(7)(A).[2]

2. The Texas Department of Agriculture had such great expectations for the benefits of Strongarm's use on Texas peanut crops that, prior to Strongarm's federal registration, it petitioned the EPA for an emergency exemption under 7 U.S.C. § 136p to permit the use of Strongarm to treat up to 184,000 acres of Texas peanuts. *See* 64 Fed. Reg. 9152 (Feb. 24, 1999).

Dow AgroSciences has sold Strongarm only with its EPA-accepted label attached to the containers of the product. Petitioners purchased Strongarm from their respective local agricultural chemical suppliers and applied it to their year 2000 peanut crops.

Petitioners misstate the facts when they argue that "Strongarm . . . was the only herbicide applied to the farmers' crops in the 2000 growing season." Pet. at 2. In fact, the great majority of the Petitioners used at least one other herbicide, and several of them used three or more different herbicides in addition to Strongarm on their 2000 peanut crops.

Petitioners further misstate the facts by arguing "[p]retrial discovery indicated that Strongarm causes injury to peanut roots in soils with pH levels of 7.0 or greater, and that before the herbicide's release, Dow was aware of the harmful effect of applying Strongarm to peanuts grown in the high pH-level soils of Texas, New Mexico and Oklahoma." *Id.* First, no pre-trial discovery was undertaken in this case, the District Court decided Dow AgroSciences' motion for summary judgment before discovery commenced.[3] Second, there is no evidence in this record to support Petitioners' accusation.

Due to extremes in weather, the year 2000 was a challenging one for all West Texas agribusinesses, including these Petitioners. Petitioners concluded, however, that Strongarm was to blame for their disappointing crop yields and threatened to sue Dow AgroSciences in multiple, separate lawsuits to be filed in several different Texas county courts. Rather than defend itself in such multiple state court proceedings, Dow AgroSciences filed a declaratory judgment action in the federal District Court most geographically convenient to the Petitioners. One month later, Petitioners filed suit against Dow AgroSciences in ten different Texas county courts, joining non-diverse Texas defendants, exactly as they had threatened to do.

The District Court denied Petitioners' motion to dismiss or to abstain from deciding Dow AgroSciences' declaratory

3. The Petitioners did not move the District Court to delay its ruling on Dow AgroSciences' motion to permit them to take discovery pursuant to Rule 56(f) of the Federal Rules of Civil Procedure.

judgment action. *See Dow AgroSciences LLC v. Bates*, NO. CIV. A. 5:01-CV-331-C, 2002 WL 1205133 (N.D. Tex. March 12, 2002).[4] The District Court then granted summary judgment against Petitioners on their counterclaims, holding almost all of them to be FIFRA-preempted, and the remainder of them barred by the limitation of remedies provision on the Strongarm label and its effective disclaimer of express and implied warranties. 205 F. Supp. 2d 623. The Fifth Circuit affirmed, but held that FIFRA preempted all of the Petitioners' claims. 332 F.3d 323. Petitioners waived appellate review of the District Court's holding on the limitation of remedies on Strongarm's label. 332 F.3d at 332 n.15.

Following the Fifth Circuit's affirmance, several of the Petitioners resumed active prosecution of their parallel state court actions. On October 14, 2003, however, the District Court enjoined the Petitioners from further prosecution of their state law actions and Petitioners have appealed that injunction to the Fifth Circuit.

REASONS FOR DENYING THE PETITION

I. The Particular Facts Of This Case Make It An Exceedingly Poor Candidate For Review.

A. Even If The Texas Supreme Court's Interpretation Of FIFRA Preemption Were Adopted Over The Fifth Circuit's Interpretation, Petitioners' Claims Would Still Be Preempted Because The "Exception To Preemption" Created In *Geye* Does Not Apply To These Facts.

Petitioners are wrong to argue that review is required because their label-related claims would have survived FIFRA preemption under the Texas Supreme Court's decision in *Am. Cyanamid Co. v. Geye*, 79 S.W.3d 21 (Tex. 2002), *cert. denied*, 123 S. Ct. 2637 (2003). The Texas court held in *Geye* that the claims presented there were not FIFRA-preempted because "[t]he EPA did not evaluate whether the tank-mixed Pursuit-Prowl combination had a toxic effect on peanut plants." *Id.* at 26. The *Geye* court held: "[T]he scope of FIFRA's preemption is dependent on what the EPA regulates, . . ."

4. Petitioners do not seek review of the Fifth Circuit's holding that the District Court did not abuse its discretion in this regard.

Id. at 29. *Contra Bates*, 332 F.3d at 330 ("Nowhere in FIFRA's text is § 136v(b)'s express preemptive command . . . linked to the interplay of EPA regulations."). *See also id.* at 331 ("FIFRA's express preemption clause is self-executing."). Because of the facts of this particular case, however, the analytical disagreement between *Geye* and *Bates* is irrelevant.

Unlike the older herbicides at issue in *Geye*, Strongarm's application for registration under the EPA's new procedures established by the Reduced Risk Initiative required Dow AgroSciences to submit a comprehensive body of data on Strongarm's efficacy and safety for use on peanut crops. The EPA considered that data and approved a label warning specifically addressing soil pH factors as affecting crop safety. Whether those warnings were adequate and sufficient in Petitioners' view does not change the fact that the EPA affirmatively exercised its regulatory authority on precisely the issues Petitioners challenge. The "exception to preemption" created in *Geye*, therefore, simply does not apply to the facts of this particular case.

B. Petitioners' Claims Are All Label-Based Because Their Other Claims All Failed As A Matter Of Texas State Law.

Petitioners are wrong to argue that review is required because of allegedly differing analyses employed by the courts when determining whether a state-law claim is merely a disguised (hence preempted) challenge to a product label. Pet. at 19-27. Petitioners argue that their pleading of an extravagant variety of claims supports the necessity of review. This Court, however, commands that the preemptive force of federal statutes may not be evaded by mere pleading tactics. *Chicago & North Western Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 324 (1981) ("[C]ompliance with the [pre-emptive] intent of Congress cannot be avoided by mere artful pleading."). More important, Petitioners' failure to offer proof on essential elements of their state-law claims proves, by process of elimination, that all their claims were label-based and that, therefore, their lengthy discussion of differing "tests" for preemption is irrelevant. Petitioners' default on this point results in a waiver of the arguments they make to this Court.

Petitioners did not offer proof that there was a safer, feasible alternative design for Strongarm's chemical composition. Accordingly, all their claims for negligent development, manufacturing and design, design-defect strict liability, and breach of implied warranty failed as a matter of black-letter Texas state substantive law. *Am. Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 437 (Tex. 1997). *See also id.* at 433 n.9; *Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 335 n.4 (Tex. 1998) (citing *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 384 (Tex. 1995)), *cert. denied*, 526 U.S. 1040 (1999); *Smith v. Louisville Ladder Corp.*, 237 F.3d 515, 521 (5th Cir.), *reh'g en banc denied*, 250 F.3d 745 (5th Cir. 2001) ("[B]ecause [Petitioners] failed to establish a safer alternative design for [Strongarm], [their] claim predicated on breach of implied warranty must fail, along with [their] design defect claim.").

Petitioners' failure to offer evidence of a safer, feasible alternative design, moreover, apparently drives their misrepresentation of a key holding in *Bates* by a cautious omission of important language immediately preceding and surrounding the snippet they pretend accurately to quote. Petitioners accuse the Fifth Circuit of dramatically expanding doctrinaire FIFRA jurisprudence, "stating that the claims were preempted because they would have the 'undeniable practical effect' of inducing a manufacturer to alter the product *or* label to avoid liability.'" Pet. at 26 (citing 332 F.3d at 329 n.9 (Petitioners' emphasis). *See also id.* at 27 (same). What the Fifth Circuit really said was that "*different* requirements may be imposed" when success on a common law claim induces a manufacturer "to alter the product or label to avoid liability" (332 F.3d at 329 n.9 (emphasis added)) and that "the farmers' claims are expressly preempted under § 136v(b) if a judgment against Dow would induce it to alter its product *label*." *Id.* at 331 (citation omitted, emphasis added).

II. This Court Has Strongly Indicated, And Nine Federal Circuits And The Courts Of Twenty-seven States Have Held, That FIFRA Expressly Preempts All Claims That Challenge A Product's EPA-Accepted Label.

A. The Text Of FIFRA § 136v(b) And Its Legislative History Confirm Congress' Preemptive Intent.

Congress enacted FIFRA in 1947, and amended it in 1972 to significantly strengthen its registration and labeling standards. *Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597, 601 (1991). The 1972 amendments ensured that FIFRA regulated the use, sale and labeling of pesticides; and that it regulated pesticides produced and sold in both intrastate and interstate commerce. *Id.* Those amendments also granted increased enforcement authority to the EPA. *Id.* In short, the 1972 amendments "'transformed FIFRA from a labeling law into a comprehensive regulatory statute.'" *Id.* (quoting *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984)).

To accomplish one principal objective of FIFRA, achieving "uniformity of labeling across the nation" (*Papas v. Upjohn Co.*, 926 F.2d 1019, 1025 (11th Cir. 1991) ("*Papas I*"), *aff'd after remand*, 985 F.2d 516 (11th Cir.) ("*Papas II*"), *cert. denied sub nom. Papas v. Zoecon Corp.*, 510 U.S. 913 (1993), Congress expressly preempted all state authority regarding pesticide labeling and packaging through 7 U.S.C. § 136v(b), entitled "Uniformity": "[A] state shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." [5]

Given the textual clarity of § 136v(b), resort to FIFRA's legislative history is not necessary. That legislative history, however, confirms Congress' preemptive intent with equal and exquisite clarity: "[T]he Committee has adopted language which is intended *to completely preempt State authority in regard to labeling* and packaging." H.R. REP. No. 92-511, at 16 (1971) (emphasis added). *See also id.* at 1-2 ("State authority to change Federal labeling and packaging is *completely preempted*.") (emphasis added); S. REP. No. 92-838, pt. 1, at 30 (1972), *reprinted*

5. The section title "Uniformity" was added through a 1988 amendment, thereby reinforcing Congress' original preemptive intent. *Papas I*, 926 F.2d at 1025.

in 1972 U.S.C.C.A.N. 3993, 4021 ("Subsection (b) *preempts any* State labeling or packaging requirements differing from such requirements under the Act") (emphasis added). Importantly, the preemption provisions which ultimately became § 136v(b) were *identical* in both the House and Senate versions of H.R. 10729. *Compare* H.R. 10729, 92d Cong. § 24(b) (1971) (House bill) *with* H.R. 10729, 92d Cong. § 23(b) (1972) (Senate version as amended). Remarkably, Petitioners neglect these dispositive expressions of preemptive intent in their discussion of FIFRA's legislative history (Pet. at 8-11), but the courts have not. *See MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 n.3 (5th Cir. 1994), *aff'd after remand*, 68 F.3d 470 (5th Cir. 1995) (mem.); *King v. E.I. DuPont de Nemours & Co.*, 996 F.2d 1346, 1349-50 (1st Cir. 1993); *Papas I*, 926 F.2d at 1023.[6]

B. This Court Recognized § 136v(b)'s Preemptive Effect In *Mortier*.

In *Mortier*, this Court construed FIFRA § 136v(a), and held that its preservation of state power to "regulate the sale or use of any federally registered pesticide or device in the State," did not preclude political subdivisions of such states from exercising that power through positive enactments of law.[7]

6. Petitioners do not just ignore this aspect of FIFRA's legislative history, they go much further by affirmatively misrepresenting it. *See* Section IIC.

7. At least thirty-five States (including Texas), however, have prohibited entirely or restricted severely the regulation of pesticides by their respective local political subdivisions. *See, e.g.*, ALA. CODE. § 2-27-5.1 (2003); ARIZ. REV. STAT. § 3-337 (2003); CAL. FOOD & AGRIC. CODE § 11501.1 (Deering 2003); COLO. REV. STAT. § 35-9-105 (2003); FLA. STAT. ch. 482.242 (2003); GA. CODE ANN. § 2-7-113.1 (2002); IDAHO CODE § 22-3426 (2003); 415 ILL. COMP. STAT. 60/3 (2003); IOWA CODE § 206.34 (2003); KAN. STAT. ANN. § 2-2480 (2002); KY. REV. STAT. ANN. § 217B.270 (Michie 2002); LA. REV. STAT. ANN. § 3:3224 (Michie 2003); MICH. COMP. LAWS § 324.8328 (2003); MINN. STAT. § 18B.02 (2002); MISS. CODE ANN. § 69-23-9 (2003); MO. REV. STAT. § 281.005 (2003); MONT. CODE ANN. § 80-8-120 (2002); NEB. REV. STAT. § 2-2625 (2002); NEV. REV. STAT. § 586.230 (2003); N.H. REV. STAT. ANN. § 430:49 (2002); N.M. STAT. ANN. § 76-4-9.1 (Michie 2003); N.Y. ENVTL. CONSERV. LAW § 33-0303 (Consol. 2003); N.C. GEN. STAT. § 143-465 (2003); N.D. CENT. CODE § 4-35-06.1 (2003); OHIO REV. CODE ANN. § 921.23(C) (Anderson 2003); OKLA. STAT. tit. 2, § 3-85 (2002); OR. REV. STAT. § 634.057 (2001); 3 PA. CONS. STAT. § 111.57 (2003); S.C. CODE ANN. § 46-13-30 (Law. Co-op. 2002); (Cont'd)

While the construction of § 136v(a) was the *Mortier* Court's central focus, it also addressed the preemptive effect of § 136v(b) in the context of pesticide labeling and packaging. This Court, employing a pre-*Cipollone* implied field preemption analysis, declared that state law was "impliedly usurped" in the area of pesticide labeling and packaging and that pesticide "labeling . . . fall[s] within an area that FIFRA's 'program' pre-empts." 501 U.S. at 614-15. *See also id.* at 613. Indeed, the United States Solicitor General strongly urged this Court to so hold:

> To be sure, an exclusively federal approach is necessary in certain areas of pesticide regulation. One such area is labeling. Due to the burden on commerce that would be imposed by different labeling requirements in states and localities across the country, *Congress clearly preempted all but federal regulation of labels*. Sec. 7 U.S.C. § 136v(b).

Brief for United States as *Amicus Curiae*, at 22, *Mortier*, 501 U.S. 597 (No. 89-105).[8]

Petitioners studiously ignore *Mortier*'s instructions on the preemptive effect of § 136v(b), but, again, the courts have not. The Seventh and Tenth Circuits, for instance, read *Mortier's* teachings to mandate preemption: "The Supreme Court recently noted the *absolutist* nature of FIFRA's pre-emption in the labeling and packaging context. . . ." *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 370 (7th Cir. 1993) (emphasis added); *Arkansas-Platte & Gulf P'ship v. VanWaters & Rogers, Inc.*, 959 F.2d 158, 164 (10th Cir. 1992) ("*Arkansas-Platte I*") (finding preemption and holding: "We base our holding on the language of § 136v . . . and our understanding of the Supreme Court's construction of FIFRA in *Mortier*."), *aff'd after remand*, 981 F.2d 1177 (10th Cir.) ("*Arkansas-Platte II*"), *cert. denied sub*

(Cont'd)
TENN. CODE ANN. § 43-8-114 (2003); TEX. AGRIC. CODE ANN. § 76.101 (Vernon 2003); VT. STAT. ANN. tit. 6, § 917 (2003); W. VA. CODE § 19-16A-2 (2003); WIS. STAT. § 94.701 (2002).

8. The Solicitor General recently reaffirmed the United States' formal position that § 136v(b) expressly preempts state common law in its *amicus* brief filed before this Court in *Am. Cyanamid Co. v. Geye*, 79 S.W.3d 21 (Tex. 2002), *cert. denied*, 123 S.Ct. 2637 (2003). *See* Section II I.

nom. Arkansas-Platte & Gulf P'ship v. Dow Chem. Co., 510 U.S. 813 (1993). *See also Hue v. Farmboy Spray Co., Inc.*, 896 P.2d 682, 691 (Wash. 1995) ("*The United States Supreme Court*, seven federal courts of appeal, dozens of district courts and state courts all concur: in preempting state labeling 'requirements,' Congress intended to preempt both direct labeling regulations and common law labeling duties enforced through damages actions.") (emphasis added).

C. Petitioners Mischaracterize FIFRA's Legislative History And *Mortier*.

Petitioners argue that FIFRA's legislative history demonstrates that Congress did not intend to preempt state tort law because the EPA's former General Counsel, John Quarles, testified regarding an early draft of a proposed amendment in 1971 that it "does not affect tort liability." Pet. at 9. This is a grave mischaracterization of what actually occurred.

First, the bill about which Mr. Quarles was testifying, H.R. 4152 (introduced February 10, 1971), did not even contain a preemption provision. It was a later House bill, H.R. 10729 (introduced on September 16, 1971), that contained a preemption provision. H.R. 10729, 92d Cong. § 24(b) (1971). *Second*, Mr. Quarles' testimony addressed a hypothetical tort action between two farmers for crop damage due to misapplication of a pesticide and had nothing to do with preemption of state law challenges to EPA-approved labeling. *See Federal Pesticide Control Act of 1971: Hearings Before the House Committee on Agriculture*, 92d Cong. 8, at 42 (1971). Petitioners' mischaracterization of Mr. Quarles' testimony is misleading and disingenuous and they compound their errors by mischaracterizing this Court's discussion of FIFRA's legislative history in *Mortier*.

Not only do Petitioners pretend away *Mortier*'s endorsement of § 136v(b)'s preemptive effect (501 U.S. at 614-15), they materially misrepresent *Mortier*'s holdings, arguing: "As noted by this Court, the Committee Reports underlying FIFRA's preemption clause are contradictory at

best. *Mortier*, 501 U.S. at 609-10." Pet. at 10.[9] The legislative histories the *Mortier* Court was discussing, however, were the antecedents of § 136v(a), not the legislative history of § 136v(b). The issue discussed, moreover, was not the preemptive effect of § 136v(b), but whether § 136v(a) preempted regulatory action by political subdivisions of states through positive enactments of law.

Petitioners' discussion of the legislative history that they pretend relates to § 136v(b), but which in truth relates to § 136v(a), is further misleading because the legislative history they discuss relates only to FIFRA's well-established and comprehensive regulatory partnership between the federal government and the states' respective administrative and executive agencies. *See* Pet. at 9-10. To accommodate "regional and local factors like climate, population, geography, and water supply" (501 U.S. at 614), "FIFRA implies a regulatory partnership between federal, state *and* local governments." *Id.* at 615 (original emphasis). *See also id.* at 601-02. Each of the states, and the District of Columbia, has joined this comprehensive federal/state regulatory partnership by enacting their own regulatory regimes to govern the sale and use of pesticide products within their own borders, but the limitations of space do not permit a comprehensive citation to each of them on this point.

This massive body of state legislative action confirms that Congress' use of the terms "regulate" and "regulation" in § 136v(a)'s preservation of state authority over pesticide sales and use detracts in no way from the federal preemption of state law "requirements," as used in § 136v(b), with respect to EPA-approved labeling.

> Read against the backdrop of regulatory activity undertaken by state legislatures and federal agencies in response to [the enactment of FIFRA], the term "regulation" most naturally refers to positive enactments by those bodies, not to common-law damages actions.

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9. Petitioners' statement here is demonstrably false because the preemption provisions that ultimately became § 136v(b) were identical in both the House and Senate versions of H.R. 10729. *See* Section IIA.

Cipollone, 505 U.S. at 519. It follows from *Mortier* and *Cipollone*, therefore, that the terms "regulate" and "regulation" in § 136v(a)'s preservation of state authority "to regulate the sale or use of" pesticides through "regulation" mean positive enactments of law and administrative agency action, not state "regulation" of pesticide labeling through imposing state "requirements for labeling . . . in addition to or different from those required under" FIFRA, either through positive enactments of law or common law tort actions, the domain expressly preempted by § 136v(b). Otherwise, the enactment of § 136v(b) "would have been doubly superfluous given FIFRA's historic focus on labeling to begin with." *Mortier*, 501 U.S. at 613 (citation omitted). *E.g., Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 454 (2002) ("We refrain from concluding here that the differing language in the two subsections has the same meaning in each. We would not presume to ascribe this difference to a simple mistake in draftsmanship.") (internal quotation marks and citation omitted); *United States v. Locke*, 529 U.S. 89, 106 (2000) ("We decline to give broad effect to savings clauses where doing so would upset the careful regulatory scheme established by federal law.") (citations omitted).

D. This Court Has Indicated That Its Enforcement Of The Self-Executing Express Preemption Clause Of The 1969 Cigarette Act In *Cipollone* Drives The FIFRA Preemption Analysis.

In *Cipollone*, decided the next term after *Mortier*, the Court construed § 5(b) of the 1965 Federal Cigarette Labeling and Advertising Act (the "1965 Cigarette Act"), and its successor, § 5(b) of the Public Health Cigarette Smoking Act of 1969 (the "1969 Cigarette Act").[10] Writing for the plurality, Justice Stevens concluded that the text of the 1969 Act mandated express preemption of state law failure to warn claims and that there was "no cause to look beyond" that text. 505 U.S. at

10. Section 5(b) of the 1969 Cigarette Act provides: "(b) No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Chapter." 15 U.S.C. § 1334(b).

517 (Stevens, J.). Justice Blackmun agreed "that the preemptive scope of the Federal Cigarette [Acts] is 'governed entirely by the express language' of the statutes' pre-emption provisions. *Ante*, 505 U.S. at 517." 505 U.S. at 531-32 (Blackmun, J.).[11] Justice Scalia separately wrote, "The proper rule of construction for express preemption provisions is, it seems to me, the one that is customary for statutory provisions in general: Their language should be given its ordinary meaning." 505 U.S. at 548 (citations omitted) (Scalia J.). Justices Scalia and Thomas read the preemptive effect of these statutes more broadly than Justice Stevens and "believe[d] petitioner's failure-to-warn claims [were] preempted by the 1965 Act, and *all* his common-law claims by the 1969 Act." *Id.* (emphasis added).

The key distinction between the preemption clauses in the 1965 and 1969 Acts, as the *Cipollone* plurality emphasized, was that the term "requirement," as Congress used it in the 1969 Act (and in § 136v(b)), is broader than the term "regulation." *See* 505 U.S. at 520-21 & n.19 (the 1969 Cigarette Act's preemption clause, which bars "'requirement[s] or prohibition[s] . . . imposed under State law,'" is "much broader" than its predecessor in the 1965 version of the statute, which was "concerned primarily with 'regulations' – positive enactments, rather than common-law damages actions"). For that reason, the majority of the Court agreed that Congressional preemption of state law requirements in the 1969 Cigarette Act "easily" preempted common law failure to warn claims.

Six Justices, therefore, held the express preemption clause of the 1969 Cigarette Act to be automatic and self-executing, even though the Act "allow[ed] the FTC to regulate print advertising" (505 U.S. at 520; *see also id.* at 541-42), much as FIFRA allows the EPA to regulate pesticide labeling. *See* 40 C.F.R. Part 156 (2003). And a unanimous Supreme Court "held that as long as a federal statute contains an express preemption clause, it is wholly unnecessary and inappropriate to import notions of implied preemption through conflict [let alone conflict with underlying agency regulatory action] into

11. Justice Blackmun's disagreement was with the majority's holdings that the term "'State law' as used in § 5(b)" of the 1969 Act included state common law. 505 U.S. at 535.

the express preemption analysis." *Bates*, 332 F.3d at 329-30 (construing *Cipollone*, footnotes omitted). *See* 505 U.S. at 517 ("[T]he other provisions of the 1965 and 1969 Acts offer no cause to look beyond § 5 of each Act.").

Thus, as this Court later explained in *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869-74 (2000), implied conflict preemption principles arising from regulatory action by federal agencies may provide *additional* bases for federal preemption, compel preemption more *broadly* than the terms of an express preemption clause, or *trump* a statutory savings clause; but an express preemption clause stands on its own legs and does not need the importation of implied conflict principles to support it. *E.g., Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1204 (9th Cir. 2002) (FIFRA's underlying regulatory structure provides reasons for preemption under ordinary conflicts principles in addition to and beyond § 136v(b)'s express preemptive mandate).[12]

Shortly after deciding *Cipollone*, this Court vacated the implied FIFRA preemption decisions in *Papas v. Upjohn Co.*, 926 F.2d 1019 (11th Cir. 1991) ("*Papas I*") and *Arkansas-Platte & Gulf P'ship v. Van Waters & Rogers, Inc.*, 959 F.2d 158 (10th Cir. 1992) ("*Arkansas-Platte I*"), and "remanded [them] . . . for further consideration in light of *Cipollone*." *Papas v. Zoecon Corp.*, 505 U.S. 1215 (1992); *Arkansas-Platte & Gulf P'ship v. Dow Chem. Co.*, 506 U.S. 910 (1992). Thus, "[t]he Supreme Court itself has indicated that *Cipollone* applies to FIFRA preemption determinations." *King v. E.I. DuPont de Nemours & Co.*, 996 F.2d 1346, 1349 (1st Cir. 1993); *Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555, 559 (9th Cir. 1995) (same).

On remand in *Papas II*, the Eleventh Circuit compared § 136v(b) with § 5(b) of the 1969 Cigarette Act and squarely

12. This was the sole point of disagreement between the Fifth Circuit's decision below and the Texas Supreme Court's decision in *Am. Cyanamid Co. v. Geye*, 79 S.W.3d 21 (Tex. 2002), *cert. denied*, 123 S.Ct. 2637 (2003). *Compare Bates*, 332 F.3d at 330 ("Nowhere in FIFRA's text is § 136v(b)'s express preemptive command . . . linked to the interplay of EPA regulations."); *see also id.* at 331 ("FIFRA's express preemption clause is self-executing."), *with Geye*, 79 S.W.3d at 29 ("[T]he scope of FIFRA's preemption is dependent on what the EPA regulates, . . ."). Because of the facts of this particular case, however, this analytical disagreement is irrelevant.

held that "the *Cipollone* opinion dictates, under an express preemption analysis, the same result we reached earlier under the implied preemption doctrine." *Papas II*, 985 F.2d at 518 (citing *Papas I*, 926 F.2d at 1026). The Tenth Circuit on remand also affirmed *Arkansas-Platte I*, and in accordance with *Cipollone's* teachings, focused on the precise text of § 136v(b) in concluding that it mandated express preemption. *Arkansas-Platte II*, 981 F.2d at 1179 ("We believe Congress circumscribed the area of labeling and packaging and preserved it only for federal law. With the same stroke, Congress banned any form of state regulation. . . .") (citing *Cipollone*, 112 S.Ct. at 2618). "Although the words employed in § 136v(b) of FIFRA are different from those in § 5(b) of the Cigarette Smoking Act, their effect is the same. . . . We see no difference between the operative effect of the two acts." *Id.* at 1179. The Seventh Circuit "discern[ed] no significant distinction at all" holding, "[n]ot even the most dedicated hair splitter could distinguish these statements." *Shaw*, 994 F.2d at 371. *See also Taylor AG*, 54 F.3d at 559; *King*, 996 F.2d at 1349. *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1024 (5th Cir. 1994) ("Applying the reasoning articulated in *Cipollone* to FIFRA and the case at hand, the conclusion is manifest: FIFRA preempts conflicting state common law concerning the improper labeling of herbicides, which is the only common law claim raised in this appeal."), *aff'd after remand*, 68 F.3d 470 (5th Cir. 1995) (mem.).

E. Petitioners Wildly Exaggerate Their Argument That "FIFRA Has Pitted Federal Judges Against State Judges."

Since *Cipollone*, there is broad agreement that the language of § 136v(b) "manifestly ordains the preemption of the establishment or enforcement of any common law duty that would impose a labeling requirement inconsistent with those established by FIFRA." *Worm v. Am. Cyanamid Co.*, 5 F.3d 744, 747 (4th Cir. 1993) ("*Worm II*") (citation and internal quotation marks omitted). Following *Cipollone*, each of the nine federal Circuits to address the issue, through at least twenty-two decisions, has easily concluded that FIFRA expressly preempts

common law challenges to the adequacy and sufficiency of pesticide labeling.[13]

Petitioners simply misstate the law by making their wildly exaggerated claim that "the confusion surrounding FIFRA has pitted federal judges against state judges." Pet. at 4. *See also id.* at 6 (decrying "the maze of conflicting case law."); *id.* ("[T]hroughout this time of confusion, FIFRA's goals of uniformity and protection of health are eviscerated."[14]); *id.* at 19 ("[F]ederal and state judges are pitted against each other in the battle over the viability of state law tort claims in pesticide-related cases.").

The true facts are these: the Supreme Courts of eighteen states, in at least twenty-five published decisions, have confirmed the fundamental rule of FIFRA preemption.[15] In an

13. *E.g., Bates*, 332 F.3d 323; *Lowe's Home Centers, Inc. v. Olin Corp.*, 313 F.3d 1307 (11th Cir. 2002), *reh'g and reh'g en banc denied*, 61 Fed. Appx. 673 (11th Cir. 2003) (table); *Netland v. Hess & Clark, Inc.*, 284 F.3d 895 (8th Cir.), *cert. denied*, 123 S.Ct. 415 (2002); *Nathan Kimmel*, 275 F.3d 1199; *Ruiz-Guzman v. Amvac Chem. Corp.*, No. 98-35088, 243 F.3d 549, 2000 WL 1763212 (9th Cir. Nov. 28, 2000); *Andrus v. AgrEvo USA Co.*, 178 F.3d 395 (5th Cir. 1999); *Hawkins v. Leslie's Pool Mart, Inc.*, 184 F.3d 244 (3d Cir. 1999); *Lescs v. William R. Hughes, Inc.*, No. 97-2278, 168 F.3d 482, 1999 WL 12913 (4th Cir. Jan. 14, 1999), *cert. denied*, 528 U.S. 1119 (2000); *Nat'l Bank of Commerce (Arnold) v. Dow Chem. Co.*, 165 F.3d 602 (8th Cir. 1999); *Kuiper v. Am. Cyanamid Co.*, 131 F.3d 656 (7th Cir. 1997), *cert. denied*, 523 U.S. 1137 (1998); *Rodriguez v. Am. Cyanamid Co.*, No. 96-15752, 116 F.3d 485, 1997 WL 306430 (9th Cir. June 5, 1997); *Grenier v. Vt. Log Bldgs., Inc.*, 96 F.3d 559 (1st Cir. 1996); *Welchert v. Am. Cyanamid, Inc.*, 59 F.3d 69 (8th Cir. 1995); *Taylor AG*, 54 F.3d 555; *Lowe v. Sporicidin Int'l*, 47 F.3d 124 (4th Cir. 1995); *Bice v. Leslie's Poolmart, Inc.*, 39 F.3d 887 (8th Cir. 1994); *MacDonald*, 27 F.3d 1021; *Worm II*, 5 F.3d 744; *King*, 996 F.2d 1346; *Shaw*, 994 F.2d 364; *Papas II*, 985 F.2d 516; *Arkansas-Platte II*, 981 F.2d 1177.

14. Petitioners do not explain, because they cannot explain, why allowing their common law challenges to Strongarm's EPA-approved label in a crop damage case would promote rather than "eviscerate" "FIFRA's goals of uniformity and protection of health." Common law litigation over EPA-approved product labeling would destroy FIFRA's goals of achieving national uniformity in pesticide labeling and common law litigation over crop damage cases has nothing to do with the protection of health.

15. *Etcheverry v. Tri-Ag Service, Inc.*, 993 P.2d 366, 373 (Cal. 2000); *Banks v. ICI Americas, Inc.*, 450 S.E.2d 671, 676 (Ga. 1994); *Kawamata Farms, Inc. v. United Agri Prods.*, 948 P.2d 1055, 1074 (Haw. 1997); *Dow Chem. Co. v.*

(Cont'd)

additional nine states where the issue has not yet reached their respective state Supreme Courts, intermediate state courts of appeal have also confirmed the fundamental rule of FIFRA preemption.[16] Based on the particular facts of this case, therefore, nine federal Circuits and twenty-seven states

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Ebling, 753 N.E.2d 633, 635-36 (Ind. 2001); *Wright v. Am. Cyanamid Co.*, 599 N.W.2d 668, 671 (Iowa 1999); *Ackerman v. Am. Cyanamid Co.*, 586 N.W.2d 208, 213-14 (Iowa 1998); *Ackles v. Luttrell*, 561 N.W.2d 573, 579-80 (Iowa 1997); *Schuver v. E.I. Du Pont de Nemours & Co.*, 546 N.W.2d 610, 615-16 (Iowa 1996); *Clubine v. Am. Cyanamid Co.*, 534 N.W.2d 385, 387-88 (Iowa 1996); *Jenkins v. Amchem Prods., Inc.*, 886 P.2d 869, 879 (Kan. 1994), *cert. denied*, 516 U.S. 820 (1995); *Hopkins v. Am. Cyanamid Co.*, 666 So. 2d 615, 621 (La. 1996); *Hochberg v. Zoecon Corp.*, 657 N.E.2d 1263, 1266 (Mass. 1995); *Goeb v. Tharaldson*, 615 N.W.2d 800, 817 (Minn. 2000); *Eyl v. Ciba-Geigy Corp.*, 650 N.W.2d 744, 759-60 (Neb. 2002), *cert. denied*, 123 S. Ct. 2646 (2003); *Pfeifer v. E.I. Du Pont de Nemours & Co.*, 606 N.W.2d 773, 778 (Neb. 2000); *Davidson v. Velsicol Chem. Corp.*, 834 P.2d 931, 934 (Nev. 1992), *cert. denied*, 507 U.S. 1051 (1993); *Lewis v. Am. Cyanamid Co.*, 715 A.2d 967, 971 (N.J. 1998); *DiPetrillo v. Dow Chem. Co.*, 729 A.2d 677, 682 (R.I. 1999); *Eide v. E.I. Du Pont de Nemours & Co.*, 542 N.W.2d 769, 772 (S.D. 1996); *Quest Chem. Corp. v. Elam*, 898 S.W.2d 819, 820-21 (Tex. 1995); *Goodwin v. Bacon*, 896 P.2d 673, 678-81 (Wash. 1995); *All-Pure Chem. Co. v. White*, 896 P.2d 697, 703-04 (Wash. 1995); *Hue v. Farmboy Spray Co., Inc.*, 896 P.2d 682, 894-95 (Wash. 1995); *Gorton v. Am. Cyanamid Co.*, 533 N.W.2d 746, 753 (Wis. 1995), *cert. denied*, 516 U.S. 1067 (1996). The Hawaii and Idaho Supreme Courts agree with FIFRA preemption generally, but hold that it extends only to label statements required by the EPA, not to voluntary label statements. *See Walker v. Am. Cyanamid Co.*, 948 P.2d 1123, 1128 (Idaho 1997); *Kawamata Farms*, 948 P.2d at 1080. *But see Sleath v. W. Mont Home Health Servs., Inc.*, 16 P.3d 1042 (Mont. 2000), *cert. denied sub nom. Dow AgroSciences LLC v. Sleath*, 534 U.S. 814 (2001).

16. *Dillon v. Zeneca Corp.*, 42 P.3d 598, 601 (Ariz. Ct. App. 2002); *ISK Biotech Corp. v. Douberly*, 640 So. 2d 85, 89 (Fla. Dist. Ct. App. 1994); *Traube v. Freund*, 775 N.E.2d 212, 217 (Ill. App. Ct.), *appeal denied*, 787 N.E.2d 170 (Ill. 2002); *Moody v. Chevron Chem. Co.*, 505 N.W.2d 900, 903 (Mich. Ct. App. 1993); *M & H Enterprises v. Tri-State Delta Chems., Inc.*, 984 S.W.2d 175, 178 (Mo. Ct. App. 1998); *Warner v. American Flouride Corp.*, 616 N.Y.S.2d 534, 541 (N.Y. App. Div. 1994); *Hopkins v. Ciba-Geigy Corp.*, 432 S.E.2d 142, 146 (N.C. Ct. App. 1993); *Romah v. Hygienic Sanitation Co.*, 705 A.2d 841, 856 (Pa. Super. Ct. 1997), *aff'd without opinion*, 737 A.2d 249 (Pa. 1999); *Hughes v. Tennessee Seeds of Brownsville, Inc.*, 970 S.W.2d 471, 474 (Tenn. Ct. App. 1997). Duplicative intermediate state appellate court decisions, and there are many, have not been included in this listing. *But see Brown v. Chas. H. Lilly Co.*, 985 P.2d 846 (Or. Ct. App. 1999).

(including Texas) would all agree that Petitioners' claims here were properly held to be preempted. Petitioners' lamentations of a supposed "jurisprudential mare's nest" (*see* Pet. at 3, 12), therefore, are wildly exaggerated, if not demonstrably untrue.

F. This Court Reinforced The Automatic And Self-Executing Effect Of Express Preemption Statutes In *Medtronic*.

Citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), Petitioners argue that "this Court's *Medtronic* reasoning implies that where the federal government has not issued regulations specific to the product or claim at issue, state tort claims in the unregulated area will not be preempted." Pet. at 16.[17] Contrary to Petitioners' argument, however, this Court in *Medtronic* again emphasized that the preemptive force of § 5(b) of the 1969 Cigarette Act (like § 136v(b) of FIFRA) is automatic and self-executing. Justice Stevens' opinion specifically distinguished § 5(b) of the 1969 Cigarette Act from the preemption regime under the Medical Device Amendments of 1976 ("MDA"), where preemption is dependent upon the regulatory actions taken pursuant to the administration of that statute. Under the MDA:

> Congress explicitly delegated to the FDA the authority to exempt state regulations from the pre-emptive effect of the MDA – an authority that necessarily requires the FDA to assess the pre-emptive effect that the Act and its own regulations will have on state laws.

518 U.S. at 496 (citing 21 U.S.C. § 360k(b)). *See also id.* at 505-06 (Breyer, J.). Dispositively, there is no similar Congressional delegation of power to the EPA to exempt state law from preemption anywhere in FIFRA's statutory structure.

Comparing the MDA's preemptive regime to the express preemptive force of § 5(b) of the 1969 Cigarette Act, Justice Stevens emphasized: "Unlike the statute construed in *Cipollone* . . . pre-emption under the MDA does not arise directly as a

17. This argument overlooks this Court's settled jurisprudence in cases like *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374 (1992), decided the same term as *Cipollone*. *See also United States v. Locke*, 529 U.S. 89, 115 (2000) ("It is not always a sufficient answer to a claim of pre-emption to say that state rules supplement . . . federal requirements.").

result of the enactment of the statute. . . ." 518 U.S. at 496. "The territory exclusively occupied by federal law [in *Cipollone*] was defined by the text of the statute itself." *Id.* at 489 n.9. Comparing Justice Stevens' plurality opinions in *Cipollone* and *Medtronic*, therefore, illustrates the important distinction between an automatic and self-executing preemption statute like § 136v(b) and a preemption regime tied to the timing, specificity and vigor of underlying regulatory activity.

While there are many distinctions between the MDA's regulation-dependent preemptive regime and enforcement of FIFRA's express preemption clause, California's Supreme Court summarized this primary distinction upon which a massive body of authority agrees:

> *Medtronic* is distinguishable on the ground Congress gave the federal Food and Drug Administration (FDA) a unique role in determining the scope of preemption under the MDA. . . . Congress did not give the EPA an analogous role in implementing FIFRA. (See *Oliver v. Reckitt & Colman, Inc., supra*, 12 F. Supp. 2d at p. 1291 ["[T]he Court's decision in *Medtronic* was influenced by the authority given to the FDA, an authority not given to the EPA."]; *Kuiper v. American Cyanamid Co., supra*, 960 F. Supp. at p. 1384 ["FIFRA does not have a corresponding federal regulation which limits its preemptive effect . . . . Such a regulation, along with the MDA's particular statutory language, was critical to the Court's opinion in *Medtronic*."].)

Etcheverry, 993 P.2d at 373 (brackets and second ellipsis original).[18]

18. *See also, Netland*, 284 F.3d at 899 & n.4 ("[O]ur sister circuits have concluded that the established interpretation of the FIFRA preemption clause is unchanged by . . . *Medtronic*."); *Nathan Kimmel*, 275 F.3d at 1206 (rejecting argument that *Medtronic* permitted state law cause of action for "fraud on the EPA"); *Hawkins*, 184 F.3d at 250 ("[W]e do not read [*Medtronic*] as standing for the overarching premise that tort claims fall outside 'preempted requirements.'"); *Lescs*, 1999 WL 12913, at *7 ("FIFRA preemption . . . is unchanged by *Medtronic*.") (*Lescs* contains the most thorough and elaborate circuit analysis of the reasons why the *Medtronic* plurality opinion does not change the express FIFRA preemption analysis.

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G. Petitioners' Argument That Common Law Litigation Is The Only Mechanism By Which Pesticide Efficacy Is "Regulated" Is Irrelevant And Wrong.

Petitioners misstate the facts and the law by arguing that "state law tort suits are the only legal vehicle serving to regulate the efficacy of pesticides." Pet. at 7. *See also id.* at 27 ("[N]o agency or individual is regulating the efficacy of this nation's pesticides.").[19] The gist of Petitioners' argument is that when Congress ousts all state authority from a given subject matter, it must replace that preempted state authority

(Cont'd)
See 1999 WL 12913, at *4-7); *Grenier*, 96 F.3d at 563 ("It . . . is now settled by . . . *Cipollone* and [*Medtronic*], that 'requirements' in this context presumptively includes state causes of action."); *Anderson v. Dow AgroSciences LLC*, 262 F. Supp. 2d 1280, 1287 (W.D. Okla. 2003) ("[M]ost courts which have analyzed FIFRA's preemption clause after *Medtronic* agree that the established interpretation of FIFRA's preemption clause remains unaffected.") (collecting authorities); *Lucas v. Bio-Lab, Inc.*, 108 F. Supp. 2d 518, 521 n.2 (E.D. Va. 2000); *Oliver v. Reckitt & Colman, Inc.*, 12 F. Supp. 2d 1287, 1292 (M.D. Fla. 1998); *Hawkins v. Leslie's Poolmart*, 965 F. Supp. 566, 572 (D. N.J. 1997) ("*Medtronic* did not alter the law of FIFRA preemption."), *aff'd in relevant part*, 184 F.3d 244 (3d Cir. 1999); *Kuiper v. Am. Cyanamid Co.*, 960 F. Supp. 1378, 1383-84 (E.D. Wis. 1997) ("*Medtronic* simply does not alter the Court's conclusion in this case."), *aff'd*, 131 F.3d 656 (7th Cir. 1997), *cert. denied*, 523 U.S. 1137 (1998); *Koch v. Shell Oil Co.*, 173 F.R.D. 288, 289-90 (D. Kan. 1997); *Ackerman*, 586 N.W.2d at 212-13 (*Medtronic* "does not alter the law regarding preemption"); *Eyl*, 650 N.W.2d at 753 ("[W]e have already considered the effect of *Medtronic, Inc.* on the issue of FIFRA preemption in *Ackles* and determined that FIFRA preempts failure-to-warn claims."); *Ackles*, 561 N.W.2d at 580; *Pfeiffer*, 606 N.W.2d at 776; *Lewis*, 715 A.2d at 972 (*Medtronic* "does not alter the conclusion that FIFRA preempts plaintiff's failure-to-warn claim"); *Lewis v. Am. Cyanamid Co.*, 682 A.2d 724, 729 (N.J. Super. Ct. App. Div. 1996) ("*Medtronic* is not inconsistent with *Cipollone*, . . . claims based on inadequate labeling are preempted by FIFRA."), *aff'd in relevant part*, 715 A.2d 967 (N.J. 1998); *Kawamata Farms*, 948 P.2d at 1074 (citing *Medtronic* in support of holding that "the words 'requirements' in §136v(b) presumptively includes state common law tort causes of action as well as state laws and regulations."); *Sherman v. Claire Mfg. Co.*, 657 N.Y.S.2d 453, 454 (N.Y. App. Div.), *appeal dismissed in part, denied in part*, 686 N.E.2d 1361 (N.Y. 1997); *Romah*, 705 A.2d at 851-52; *Didier v. Drexel Chem. Co.*, 938 P.2d 364, 366 (Wash. Ct. App. 1997). *But see Sleath*, 16 P.3d 1042; *Brown*, 985 P.2d 846.

19. Petitioners cite *Andrus*, 178 F.3d at 399, to support this latter statement but *Andrus*, of course, says nothing of the kind.

with a corresponding federal regulatory program in order for preemption to be complete. That clearly is not the law. *E.g., Morales v. Trans World Airlines, Inc.*, 504 U.S. 374 (1992). Petitioners' argument, therefore is irrelevant under the settled jurisprudence of this Court.

Petitioners further misplace reliance on a 1978 amendment to FIFRA that, without changing a syllable of § 136v(b), permitted the EPA to selectively rather than automatically review efficacy data during the initial product registration process. Pet. at 7 (quoting 7 U.S.C. § 136a(c)(5)). From that 1978 amendment, Petitioners leap to the faulty conclusion that just because the EPA requires submission of efficacy data selectively rather than automatically during the initial registration process, it does not exercise regulatory authority over label statements concerning efficacy. To the contrary, the EPA heavily regulates efficacy issues; the discretion accorded the EPA to selectively waive the otherwise automatic and mandatory submission of such data changes only the methods of such regulation.

First, regardless of the EPA's discretionary data waiver authority during the initial registration process, pesticide registrants are nevertheless required to generate efficacy data, to balance that data with the proposed label instructions, and to hold that data ready for EPA review as it may require. 40 C.F.R. § 158.640(b)(1) (2003). If Petitioners' argument that FIFRA preemption depends upon the timing and intensity of EPA scrutiny of efficacy data were to succeed, it would have the perverse effect of forcing applicants to automatically deluge the EPA with data it neither wants nor needs in the initial registration process in order to protect themselves from that loophole in preemption.

> Such an approach would force FIFRA applicants to ensure that their disclosures to the EPA would satisfy not only the standards imposed by that agency under federal law, but also the potentially heterogeneous standards propounded by each of the 50 States. Such a holding would in turn motivate potential applicants under FIFRA to "submit a deluge of information that the [EPA]

> neither wants nor needs, resulting in additional burdens on the [EPA's] evaluation of an application." *Id.* at 351. This outcome would needlessly drain the EPA of its limited resources,
>
> . . . .

Nathan Kimmel, 275 F.3d at 1207 (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (alterations in original)).

Moreover, Petitioners ignore FIFRA's comprehensive post-registration data reporting requirements (7 U.S.C. § 136d(a)(2) and 40 C.F.R. Part 159), and the comprehensive regulation of efficacy issues by state administrative agencies.

> [T]here [are] two [more] fundamental flaws in the argument that pesticide efficacy will go "largely, or entirely, unregulated" if state failure-to-warn claims are preempted: (1) Although the EPA has waived the submission of efficacy data for agricultural pesticides at the time of their *initial* registration, the agency does require and review such data if efficacy-related problems develop later; and (2) California [like Texas] has a comprehensive registration and regulatory program for pesticides, and while the California Department of Pesticide Regulation may not impose its own requirements for labeling, it can restrict or prohibit the sale or use of products that it determines are inefficacious or phytotoxic.

Etcheverry, 993 P.2d at 375 (original emphasis). *See also id.* at 375-76 (describing EPA's comprehensive post-registration regulation); *id.* at 376 (describing California's state regulatory program). *Compare* TEX. AGRIC. CODE ANN. §§ 76.001-76.203 (Vernon 2003). *See also id.* at § 76.046(c)(3) (permitting the denial or cancellation of registration of a pesticide that is "detrimental to vegetation, except weeds"). In point of fact, the state regulatory programs of at least twenty-four states join Texas in *specifically* addressing and regulating efficacy issues.[20]

20. *See, e.g.*, ALA. CODE. § 2-27-2(24)(b)(4) (2003) (pesticide is "misbranded" if it harms "vegetation, except weeds, to which it is applied"); (Cont'd)

(Cont'd)
ARIZ. REV. STAT. § 3-341(17)(b)(vi) (Michie 2003) (pesticide is "misbranded" if it is "injurious to . . . vegetation, other than the pest to which it is applied"); ARK. CODE ANN. § 2-16-402 (2003) (one purpose of the Arkansas Pesticide Control Act is to eliminate "ineffective" pesticides); CAL. CODE REGS. tit. 3, § 6186 (2003) ("Each application for registration or amendment to the labeling of a pesticide shall be accompanied by data supporting each efficacy claim."); *id.* § 6192 (reserving right to request phytotoxicity data in considering registration); COLO. REV. STAT. § 35-9-107(1)(e) (2003) (reserving right to request full description of tests and results including "efficacy and hazard data upon which the claims are based"); CONN. GEN. STAT. § 22a-49 (2003) (reserving right to request a report regarding "tests that have been made to establish the effectiveness of the product against the pest which is to be controlled"); FLA. STAT. ch. 487.025(g) (2003) (pesticide is "misbranded" if it is "injurious to . . . vegetation, except weeds, to which it is applied"); *id.* ch. 487.041 (reserving right to require "evidence of the efficacy" of pesticides); FLA. ADMIN. CODE ANN. r. 5E-2.031 (2003) (state agency may require submission of "summaries of data from pesticide efficacy studies" in registering pesticides); IND. CODE ANN. § 15-3-3.5-2(19)(b)(vii) (Michie 2003) (pesticide is "misbranded" if it is "injurious to . . . vegetation, except weeds, to which it is applied"); MD. CODE ANN., AGRIC. § 5-101(q)(8) (2002) (same); MISS. CODE ANN. § 69-23-3(bb)(viii) (2003) (same); MONT. CODE ANN. § 80-8-102(25)(b)(vii) (2002) (same); NEV. REV. STAT. ANN. § 586.180(2)(g) (Michie 2003) (same); N.Y. ENVTL. CONSERV. LAW § 33-0101(32)(g) (Consol. 2003) (same); N.Y. COMP. CODES R. & REGS. tit. 6, § 326.14(h) (2003) (reserving right to collect "product effectiveness data" for pesticides); N.C. GEN. STAT. § 143-435 (2003) (one purpose of the North Carolina Pesticide Law of 1971 is "[m]ore extensive observation, study and monitoring of the effectiveness and the use of pesticides . . . ."); *id.* § 143-460(23)(b)(7) (pesticide is "misbranded" if it is "injurious to . . . vegetation, except weeds, to which it is applied"); N.D. CENT. CODE § 19-18-2(19)(b)(10) (2003) (same); OKLA. STAT. tit. 2, § 3-81(28)(b)(7) (2003) (same); R.I. GEN. LAWS § 23-25-3 (2002) (one purpose of the Pesticide Control Act is to ensure that pesticides are not "ineffective"); S.D. CODIFIED LAWS § 38-20A-4 (Michie 2003) (secretary may request "efficacy" data from the applicant); TENN. CODE ANN. § 43-8-102(10)(G) (2003) (pesticide is "misbranded" if it is "injurious to . . . vegetation, except weeds, to which it is applied"); *id.* § 43-8-104(b); TEX. AGRIC. CODE ANN. § 76.046(c)(3) (Vernon 2003); 23 TEX. REG. 491 (board may approve any pesticide registered for structural pest control "as long as . . . efficacy has been demonstrated"); UTAH CODE ANN. § 4-14-3 (2003) (requiring submission of "any information prescribed by regulation of the department deemed necessary for the safe and effective use of the pesticide"); VT. STAT. ANN. tit. 6, § 911(15)(B)(vii) (2003) (pesticide is "misbranded" if it is "injurious to . . . vegetation, except weeds, to which it is applied"); VA. CODE ANN. § 3.1-249.27 (Michie 2003) (same); *id.* § 3.1-249.39 (Cont'd)

Therefore, as *Etcheverry* explained, the EPA heavily regulates efficacy issues; § 136a(c)(5) changes only the methods of that regulation. The states, too, heavily regulate efficacy issues through their respective regulatory and administrative agencies. Accordingly, Petitioners' argument against § 136v(b)'s express preemptive command, that an additional layer of common law tort "regulation" of pesticide efficacy is necessary to achieve FIFRA's goals, is misplaced and incorrect. *Gade v. National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 103 (1992) ("[I]t is not enough to say that the ultimate goal of both federal and state law is the same, [a] state law is also pre-empted if it interferes with the methods by which the federal statute was designed to reach that goal.") (citations, internal quotation marks and brackets omitted). Thus, "[FIFRA] does not foreclose a state from enacting its own laws to advance the goal of [crop] safety, but it does restrict the ways in which it can do so." *Id.*

H. Petitioners' Focus On A 1978 Amendment To FIFRA Overlooks An Important Holding In *Cipollone* And FIFRA's 1988 And 1996 Amendments.

By focusing on the 1978 amendment to FIFRA, Petitioners also overlook *Cipollone's* holding that "the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one." 505 U.S. at 520 (quoting *United States v. Price*, 361 U.S. 304, 313 (1960)). "Plaintiff's reliance on subsequent legislative history showing an intent that common-law causes of action are not preempted is also misplaced. The plain language of § 136v(b) and its legislative history show a preemptive intent, and subsequent legislative history cannot negate that intent." *Jenkins v. Amchem Prods., Inc.*, 886 P.2d 869, 879 (Kan. 1994), *cert. denied*, 516 U.S. 820 (1995).

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(reserving right to require data on "product efficacy"); WASH. REV. CODE § 15.58.130(2)(d)(iv) (2003) (pesticide is "misbranded" if it does not contain directions, warnings, or cautionary statements necessary to protect "useful vegetation"); W. VA. CODE § 19.16A-3(27)(H) (2003) (pesticide is "misbranded" if it is "injurious to . . . vegetation to which it is applied" except weeds). The limitations of space do not permit further citation to state regulatory programs addressing efficacy issues more generally, rather than with the specificity of the cited state regulatory provisions.

Moreover, assuming subsequent Congressional action may illuminate the preemptive intent of a prior Congress, Petitioners' argument defeats itself because in concentrating on a 1978 amendment, they overlook the fact that a 1988 Congress reinforced the 1972 Congress' express preemptive command by adding the heading "Uniformity" to § 136v(b) without changing the language of the statute. *Papas I*, 926 F.2d at 1025.

> Of equal significance is the fact that Congress has remained silent in the face of *Cipollone* and its FIFRA progeny. If the interpretation of congressional purpose by so many courts were incorrect, Congress could enact corrective legislation. Its silence here – in the face of a uniform, widespread and rapidly growing wave of precedent – may be deemed a conscious acquiescence in the conclusion we and others have reached.

Hue v. Farmboy Spray Co., Inc., 896 P.2d 682, 691 (Wash. 1995) (citations omitted). Indeed, on August 3, 1996, a year after *Hue*, Congress amended and re-enacted FIFRA through the Food Quality Protection Act of 1996, and left its express preemption clause undisturbed. Congressional silence in 1996, in light of overwhelming federal and state law finding preemption since *Cipollone*, is thunderous in its effect.

I. The United States Solicitor General And The EPA Have Expressly Repudiated The Prior Anti-Preemption Arguments Made In *Etcheverry*.

Petitioners are wrong to rely upon and argue from the unsuccessful *amicus curiae* brief filed by the EPA and the Environmental and Natural Resources Division of the United States Department of Justice (not the United States Solicitor General, as Petitioners incorrectly argue, Pet. at 4, 21) before the California Supreme Court in *Etcheverry*, an abbreviated version of which was filed in *Hart v. Bayer Corp.*, 199 F.3d 239 (5th Cir. 2000), to support their argument that FIFRA does not preempt state law causes of action against herbicide

manufacturers that challenge the accuracy and sufficiency of EPA-approved product labels. *See* Pet. at 4, 11-12, 21-22.[21]

First, as Petitioners concede (Pet. at 5, 21) the United States Solicitor General has directly repudiated the EPA's former position on FIFRA preemption in its recent *amicus curiae* brief before this Court in *Am. Cyanamid Co. v. Geye*, 79 S.W.3d 21 (Tex. 2002), *cert. denied*, 123 S.Ct. 2637 (2003), stating in part:

> The United States has re-examined the position that it urged in *Etcheverry* in light of the ruling of the California Supreme Court in that case, as well as the subsequent rulings of other courts, and it has concluded that its position in *Etcheverry* that FIFRA categorically does not preempt common law tort suits or other damages actions is incorrect. In the United States' view, just as Section 136v(b) applies to requirements imposed in a law enacted by a legislature or a regulation promulgated by a state agency, it applies to requirements imposed in the form of a duty or standard of care in a tort action.

Brief for United States as *Amicus Curiae*, at 17, *Geye*, 79 S.W.3d 21 (No. 01-0008) (footnote omitted). *See also id.* at 9 ("[T]he United States submits that state-law damages claims are within the scope of Section 136v(b) where the state-created legal duty on which the suit is predicated would 'impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under [FIFRA].'") (second alteration in original, quoting § 136v(b)).

Unable and unwilling to deal with the United States' unequivocal endorsement of FIFRA preemption in a straightforward way, Petitioners instead suggest the EPA might not agree with the Solicitor General because its separate counsel did not sign the *Geye amicus* brief as it had done with

21. The EPA's litigation arguments in *Etcheverry* were automatically suspect because the Solicitor General took a directly contrary position in *Mortier*, telling this Court that "an *exclusively federal approach* is necessary in certain areas of pesticide regulation. *One such area is labeling.*" Brief for United States as *Amicus Curiae*, at 22, *Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597 (No. 89-105) (emphasis added). Indeed, the EPA did not even acknowledge in *Etcheverry* the Solicitor General's prior emphatic support for preemption in *Mortier*.

the earlier *Etcheverry amicus* brief. Pet. at 21-22. Not only is this suggestion preposterous, it is factually erroneous. On October 6, 2003, the EPA issued a press release specifically endorsing and agreeing with the Solicitor General's *Geye amicus*:

> [FIFRA] preempts States from imposing any requirements for labeling or packaging that are in addition to or different from Federal law. Accordingly, crop damage lawsuits that impose label requirements that are different from the Federal label requirements are preempted. The Federal government took this position in a brief to the United States Supreme Court. The overwhelming majority of courts that have considered this issue agree with this legal interpretation.
>
> EPA has a comprehensive regulatory program for pesticides, and in particular has extensive requirements for national product labeling. Every pesticide product sold in the United States must bear an EPA-approved label containing cautions and use directions to ensure its safe and effective use. The Agency's position on preemption is consistent with the longstanding health and safety requirements imposed by the Federal pesticide laws. It also reaffirms the longstanding position that FIFRA, which establishes a stringent national regulatory program, is the guiding and preeminent regulatory system.

Press Release, Environmental Protection Agency (Oct. 6, 2003) (quoted in part in Mary Beth Polley, *EPA: FIFRA Preempts Labeling-Related Tort Lawsuits*, 31 PESTICIDE & TOXIC CHEM. NEWS 20 (Oct. 13, 2003)).

J. Petitioners Either Flatly Misstate The Law Or Grossly Exaggerate Their Arguments That A Conflict In Lower Court Authority Exists Requiring Resolution By This Court.

1. Petitioners misstate the law by arguing that the D.C. Circuit's obsolete and repudiated *Ferebee* decision represents an inter-circuit conflict.

Petitioners misstate the law by arguing that the District of Columbia Circuit's obsolete decision in *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir. 1984), demonstrates a conflict between that Circuit and its nine sister Circuits that, since *Cipollone*, have enforced FIFRA's express preemption clause. *See* Pet. at 3 n.1; 13; 19-20. *Ferebee* was discussed in *Cipollone* itself (505 U.S. at 536-37), but a majority of the Court rejected *Ferebee*'s anti-preemption thesis, holding it to be "at odds with the plain words of the 1969 Act and with the general understanding of common-law damages actions." 505 U.S. at 521 (plurality opinion); *id.* at 548-49 (Scalia, J.). Petitioners' discussion of *Ferebee* collides directly with *Cipollone*'s majority and the massive weight of post-*Cipollone* authority:

> *Ferebee*'s fundamental thesis – that liability under state law for failure to warn is not a requirement for labeling or packaging different from that required under FIFRA – has been rejected by the federal courts since *Cipollone* as "sophistry" and "silly," and the attempted distinction has been characterized as "illusory."

Etcheverry, 993 P.2d at 371-72 (collecting authorities, internal citation omitted).

Petitioners compound their error by stating that "[t]he *Ferebee* opinion has never been revisited by the [D.C. Circuit] court, . . ." Pet. at 20. This is simply not true.

> Although the District of Columbia Circuit has not expressly overruled *Ferebee*, it has expressly acknowledged that *Cipollone* repudiated its central premise by "explaining that damage actions can be used to enforce state regulations as effectively as other forms of preventive relief and thus damage actions must be preempted where positive enactments are preempted . . . ." (*Waterview Management Co. v. F.D.I.C.* (D.C. Cir. 1997) 105 F.3d 696, 699 [summarizing *Cipollone's* holding]).

Etcheverry, 993 P.2d at 372 (alterations original).

2. Petitioners misstate the law by arguing that a conflict has arisen between the state and federal courts in New York since this Court's *Medtronic* decision.

Petitioners also flatly misstate the law when they argue that a conflict between the state and federal courts in New York has emerged because of *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). *See* Pet. at 19-21; *id.* at 27 (citing *Tyler v. Dow Chem. Co., Inc.*, 683 N.Y.S.2d 619 (N.Y. App. Div. 1998), and *Mann v. H.W. Anderson Prods., Inc.*, 676 N.Y.S.2d 658 (N.Y. App. Div. 1998)).

First, neither the *Tyler* nor *Mann* court even mentioned *Medtronic*. Second, the *Tyler* court expressly held that "plaintiffs' allegations concerning the failure to provide additional or different warnings than those contained on the label are preempted by FIFRA." 683 N.Y.S.2d at 621 (citation omitted). Similarly, the *Mann* court agreed that product manufacturers are entitled to FIFRA preemption, but held that Anderson, the employer of plaintiff's mother, had no standing to assert that defense under the specific facts alleged. *See* 676 N.Y.S.2d at 660 ("The complaint in *Warner* was directed solely at the manufacturers, who relied successfully on the FIFRA labeling preemption. Although Union Carbide [the manufacturer] fits fully within the *Warner* holding and the FIFRA labeling preemption, we conclude, for the reasons that follow, that Anderson does not."). Third, New York's state courts have expressly *rejected* the notion that *Medtronic* alters the FIFRA preemption analysis. *Sherman v. Claire Mfg. Co.*, 657 N.Y.S.2d 453, 454 (N.Y. App. Div.) (FIFRA precedent "not inconsistent with . . . *Medtronic*"), *appeal dismissed in part, denied in part*, 686 N.E.2d 1361 (N.Y. 1997). *See also Ell v. S.E.T. Landscape Design, Inc.*, 729 N.Y.S.2d 515, 517 (N.Y. App. Div. 2001).

Petitioners' argument that a conflict has emerged between the federal and state courts in New York since *Medtronic*, therefore, is simply false. *Compare Williams v. Dow Chem. Co.*,

255 F. Supp. 2d 219, 228 (S.D.N.Y. 2003) ("Defendants convincingly argue that common law tort claims based on 'fraudulent omission,' 'fraudulent concealment' or 'failure to warn' are preempted by FIFRA.") *with Tyler*, 683 N.Y.S.2d at 621, *and Ell*, 729 N.Y.S.2d at 517.

3. Petitioners cannot rely on the Arkansas Supreme Court's obsolete decision in *Alter* to support their "conflict" argument.

Petitioners cannot rely on the Arkansas Supreme Court decision in *Ciba-Geigy Corp. v. Alter*, 834 S.W.2d 136 (Ark. 1992), to bolster their exaggerated claims of conflict. *See* Pet. at 6, 21. The Arkansas Supreme Court in *Alter* relied on *Ferebee's* holdings and delivered its decision a scant twenty-eight days before this Court issued its seminal decision in *Cipollone*, in which a majority of this Court, as demonstrated above, flatly rejected *Ferebee's* anti-preemption thesis. There is every reason to believe, therefore, that the Arkansas Supreme Court is ready to revisit its *Alter* decision in light of *Cipollone* and its FIFRA-related progeny. *See Goforth v. Smith*, 991 S.W.2d 579, 584 (Ark. 1999) ("In *Cipollone* . . . the Supreme Court wrote '[A]t least since *Erie R. Co. v. Tompkins* . . . we have recognized the phrase 'state law' to include common law as well as statutes and regulations.'") (original brackets).

CONCLUSION

The petition for writ of certiorari should be denied.

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No. 03-388

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In The
Supreme Court of the United States

DENNIS BATES; JIMMY BURSON; BENNY JUDAH, doing business as CLEARWATER FARMS; TOMMY COLEMAN; RICHARD COX; WAYNE DAVIS; NEIL FRIESSEN; JAKE FROESE; THOMAS FUSTON; ARTHUR GALVAN, doing business as G-5 PARTNERSHIP; GREG HUGHES, doing business as JH CATTLE CO.; RUDY KLASSEN; RONNIE LOVE; KEVIN MATHIS; BRAD PALMER; KIRK PARRISH, doing business as K-L FARMS; JERRY PARRISH; JOEVELYN PATTERSON and DONALD GRUBEN; STACEY PRICE; BENNY JUDAH, doing business as PEA-COT FARMS; BILLY SHANNON; FLOYD STOKES; CRAIG WEST; FRENCHIE LEE WHEELER,

Petitioners,

versus

DOW AGROSCIENCES LLC,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

SUPPLEMENTAL BRIEF IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Which, if any, state law crop injury claims are preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-137?

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AMICUS BRIEFS:

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OTHER AUTHORITIES:

OFFICE OF PESTICIDE PROGRAMS, U.S. EVTL. PROT. AGENCY, PESTICIDE REGULATION NOTICE 96-4 § 3 (June 3, 1996) 2

OFFICE OF PESTICIDE PROGRAMS, U.S. EVTL. PROT. AGENCY, PESTICIDE REGULATION NOTICE 97-3 (Sept. 4, 1997) 2

REASONS FOR GRANTING THE PETITION

In submitting its recommendation to this Court, the Solicitor General makes three assumptions. First, it assumes that Strongarm was registered and approved under 7 U.S.C. § 136a(c)(10), known as the Reduced-Risk Initiative ("RRI"). Second, it assumes that in the registration process, Respondent submitted efficacy testing data to the EPA. Finally, it assumes that the RRI process constitutes a regulation of efficacy. Petitioners assert that all three assumptions are wrong.

Regarding the first assumption, on page 16 of its Amicus Brief, the Solicitor General relies upon unsupported statements in Respondent's Brief in Opposition which claim that Strongarm was approved under the RRI.[1] Due to continuing proceedings before the Fifth Circuit, Petitioners no longer have access to the record to verify this claim. However, Petitioners do not believe that the record indicates that Strongarm was approved under the RRI. Evidence was admitted against Respondent in other litigation showing that Strongarm was not approved under the RRI, but rather was approved under a different fast track program for registration of conventional pesticides after being denied registration under the RRI.

[1] The Solicitor General finds this statement important because it supports the contention that the federal government regulates product efficacy in the pesticide approval process. Additionally, the Solicitor General uses Respondent's assertion that Strongarm was registered under the RRI to diminish the conflict between this case and the Texas Supreme Court's opinion in *American Cyanamid Company v. Geye*, 79 S.W.3d 21 (Tex. 2002), *cert. denied*, 123 S. Ct. 2637 (2003), and to show that this case does not meet the criteria for this Court to grant discretionary review.

The Solicitor General also assumes that Respondent submitted efficacy testing data in the RRI registration process. However, approval under the RRI is not contingent upon submission of efficacy data. OFFICE OF PESTICIDE PROGRAMS, U.S. EVTL. PROT. AGENCY, PESTICIDE REGULATION NOTICE 97-3 § 7 (Sept. 4, 1997). Furthermore, Petitioners believe this assumption about the data Respondent actually submitted to the EPA is unsupported by the record.

Finally, the Solicitor General assumes that the RRI process equates to EPA regulation of efficacy. An examination of the express language of Pesticide Registration Notice 97-3 directly contradicts this assumption. Although the EPA does request the applicant submit efficacy data, it emphasizes "that the Agency does not expect the applicant to perform any additional testing to derive the data necessary to develop rationales for the Reduced-Risk Program." *Id.* The EPA allows the applicant the option of not submitting efficacy data and instead explaining why submission of the efficacy data is unnecessary to the approval process. *See id.* The language of the RRI makes clear that submission of efficacy data is not a requirement to approval, and approval under the RRI does not guarantee that the EPA evaluated a product's efficacy.

In 1996, the EPA reminded those in the pesticide community that the "registration requirements [that a pesticide not be misbranded] should not be read as reintroducing efficacy concerns into the label approval process. Having directly given EPA the authority to disregard efficacy issues, Congress could not have intended that, once EPA exercised this authority, the same efficacy issues would come in through the back door of the label approval process." OFFICE OF PESTICIDE PROGRAMS, U.S. EVTL. PROT. AGENCY, PESTICIDE REGULATION NOTICE 96-4 § 3 (June 3,

1996). Today, however, the Solicitor General seems to argue exactly the opposite: "Congress's 1978 Amendments to FIFRA relieved EPA of any obligation to require registrants to submit efficacy data, but it did not relieve registrants of their obligation to submit accurate labeling for approval in the registration process, or immunize registrants from FIFRA's penalties for false or misleading labeling." Brief of Amicus Curiae the United States on Petition for a Writ of Certiorari, *Bates v. Dow AgroSciences LLC*, 332 F.3d 323 (5th Cir. 2002), *petition for cert. filed*, 72 USLW 3184 (2003) (No. 03-388) (internal citations omitted).

CONCLUSION

In this area of law, courts are divided not only on the outcome of their decisions but also on the proper analysis to apply in determining which state law tort claims are preempted. This issue has created discord between the federal and state judiciary for two decades and will continue to do so until settled by this Court. This Court has always recognized the dangers inherent in the separate state and federal legal systems.

> Understandably this dual court system was bound to lead to conflicts and frictions. Litigants who foresaw the possibility of more favorable treatment in one or the other system would predictably hasten to invoke the powers of whichever court it was believed would present the best chance of success. Obviously, this dual system could not function if state and federal courts were free to fight each other for control of a particular case.

Atl. Coast Line R.R. Co. v. Bhd. of Locomotive Eng'rs, 398 U.S. 281, 286 (1970). The assumptions made by the Solicitor General are inconsistent with the record evidence and the language of the relevant EPA provisions. This case presents the proper set of facts to make a final determination on an important question of federal law that has not been, but should be, settled by this Court.

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No. 03-388

IN THE

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Petitioners,

v.

DOW AGROSCIENCES LLC,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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STATEMENT PURSUANT TO RULE 29.6

Dow AgroSciences LLC is a wholly owned subsidiary of The Dow Chemical Company.

Petitioners' response to the Brief for the United States as *Amicus Curiae*, their Supplemental Brief in Support of Petition for a Writ of *Certiorari* ("Supplemental Brief"), simply ignores the United States' fundamental and primary position; that is, 7 U.S.C. § 136v(b), the express preemption clause in the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y, operates automatically and unconditionally, making no exceptions dependent upon the timing or intensity of the Environmental Protection Agency's ("EPA") scrutiny of product efficacy or crop safety data. *See Amicus* Brief at 10-11 ("Under Section 136v(b)'s plain text, EPA's decision not to require manufacturers to submit efficacy information as part of the registration process is not relevant to the scope of FIFRA's express preemption."); *id.* at 12 ("Section 136v(b)'s unqualified text does not exempt from preemption state-law damages actions based on product efficacy."); *id.* at 13 ("EPA's general practice of not independently evaluating product efficacy data is irrelevant to Section 136v(b)'s express preemption inquiry."); *id.* at 14 ("Section 136v(b)'s proscription continues to prohibit a State from requiring the registrant to change the directions for use or to include additional or different product efficacy statements on the label, regardless of whether or not EPA evaluates product efficacy claims in the registration process."); *id.* at 17 n.9 ("Under a proper reading of Section 136v(b), the question whether EPA received or reviewed efficacy data is irrelevant to the express preemption inquiry.").

Further, Petitioners' Supplemental Brief mischaracterizes 7 U.S.C. § 136a(c)(10). Contrary to Petitioners' suggestion, Section 136a(c)(10) is not a provision under which product registrations issue. Rather, it authorizes instead a process for expedited review of certain registration applications,

according priority consideration to applications submitted under EPA's Reduced Risk Initiative. *See Amicus* Brief at 16 n.5 (describing Section 136a(c)(10)'s expedited review procedures).

Petitioners state they "do not believe Strongarm was approved under the [Reduced Risk Initiative]." Supplemental Brief at 1. Registrations, however, do not issue under Section 136a(c)(10) in the first place. Indeed, Respondents already informed this Court that Strongarm's registration issued under Section 136a(c)(7)(A):

> Because Strongarm's application for registration was submitted under the 1996 amendments to FIFRA, specifically 7 U.S.C. § 136a(c)(10) (authorizing the Reduced Risk Initiative implemented by the EPA through Pesticide Regulation Notice 97-3 (Sept. 4, 1997)), Dow AgroSciences submitted a comprehensive body of data on Strongarm's efficacy in controlling broadleaf weeds in peanuts and its safety for that use.
>
> * * *
>
> Strongarm's federal registration ultimately issued on March 8, 2000, pursuant to 7 U.S.C. § 136a(c)(7)(A).

Brief in Opposition at 2 (footnote omitted).

Petitioners also suggest that Respondent did not submit product efficacy and crop safety data to EPA during initial registration process for Strongarm, stating that "Petitioners

believe [the United States'] assumption about the data Respondent actually submitted to the EPA is unsupported by the record." Supplemental Brief at 2. The record, however, clearly reflects that Respondent did in fact submit this data to EPA. *See* 6R. 1259-62. Moreover, Petitioners ignore that EPA is a signatory to the *Amicus* Brief. EPA was and is in the best position to confirm that product efficacy and crop safety data were submitted during the Strongarm registration process, and if such data had not been submitted, EPA would be best positioned to challenge that fact and it did not. *See Amicus* Brief at 16.

Lastly, Petitioners' suggestion on this point, as the United States explained, is irrelevant to FIFRA's express preemptive effect. Thus, any debate over Respondent's data submissions to EPA ends before it begins.

CONCLUSION

For the reasons explained in Respondent's Opposition Brief, and for the reasons explained by the United States in its *Amicus* Brief, the Petition should be denied.

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In the Supreme Court of the United States

DENNIS BATES, ET AL., PETITIONERS

v.

DOW AGROSCIENCES LLC

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, preempts petitioners' state tort claims alleging that application of respondent's herbicide damaged petitioners' peanut crops.

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In the Supreme Court of the United States

No. 03-388

DENNIS BATES, ET AL., PETITIONERS

v.

DOW AGROSCIENCES LLC

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is submitted in response to the order of this Court inviting the Solicitor General to express the views of the United States. The United States submits that the court of appeals correctly ruled that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, preempts petitioners' state law tort claims. That decision, which is consistent with the largely uniform rulings of other federal courts of appeals and state courts of last resort, and turns on the characteristics of the particular state-law claims at issue, does not warrant this Court's review.

STATEMENT

Respondent Dow Agrosciences LLC filed suit in the United States District Court for the Northern District of Texas against petitioners Dennis Bates, et al., in anticipation that petitioners would bring a state court action alleging that

their application of respondent's herbicide, Strongarm, damaged their peanut crops. The district court granted respondent summary judgment, holding that FIFRA preempts most of petitioners' state tort claims and that the remaining claims are barred by product label disclaimers. Pet. App. 21a-31a. The court of appeals affirmed, ruling that FIFRA preempts all of petitioners' claims without reaching the effect of the label disclaimers. *Id.* at 1a-20a.

A. The Federal Insecticide, Fungicide, And Rodenticide Act

Congress created FIFRA through a series of enactments to regulate the labeling, sale, and use of pesticides, including herbicides. See *Wisconsin Pub. Intervenor* v. *Mortier*, 501 U.S. 597, 601 (1991). As originally enacted in 1947, see ch. 125, 61 Stat. 163, FIFRA "was primarily a licensing and labeling statute." *Mortier*, 501 U.S. at 601 (quoting *Ruckelshaus* v. *Monsanto*, 467 U.S. 986, 991 (1984)). In 1972, Congress "significantly strengthened FIFRA's registration and labeling standards" in response to "environmental and safety concerns." *Ibid.* See Federal Environmental Pesticide Control Act of 1972 (1972 Amendments), Pub. L. No. 92-516, 86 Stat. 973. In addition, Congress "regulated the use, as well as the sale and labeling, of pesticides" and granted the Environmental Protection Agency (EPA), which had previously been charged with federal oversight of pesticide programs, "increased enforcement authority." *Mortier*, 501 U.S. at 601. The 1972 Amendments effectively "transformed FIFRA from a labeling law into a comprehensive regulatory statute." *Ibid.* (quoting *Ruckelshaus*, 467 U.S. at 991). Congress has continued to amend FIFRA in response to experience gained in regulating pesticides. See, *e.g.*, Federal Pesticide Act of 1978 (1978 Amendments), Pub. L. No. 95-396, 92 Stat. 819; Food Quality Protection Act of 1996 (1996 Amendments), Pub. L. No. 104-170, Tit. II, 110 Stat. 1489.

FIFRA directs EPA to register pesticides for particular uses and to approve pesticide labels. 7 U.S.C. 136a. FIFRA provides that EPA "shall register a pesticide" if the agency determines, in light of any restrictions placed on the pesticide's use:

> (A) its composition is such as to warrant the proposed claims for it;
>
> (B) its labeling and other material required to be submitted comply with the requirements of this subchapter;
>
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
>
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

7 U.S.C. 136a(c)(5). EPA has promulgated regulations detailing the registration requirements. See 40 C.F.R. Pt. 152 *et seq.*

Based on its experience following the 1972 Amendments, EPA reported to Congress that the agency's obligation to evaluate efficacy claims in the registration process was diverting scarce resources needed to evaluate environmental and health effects. Congress responded in the 1978 Amendments, providing:

> In considering an application for the registration of a pesticide, the Administrator [of EPA] may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy.

7 U.S.C. 136a(c)(5). As a consequence of the 1978 Amendments, EPA's regulations governing registration of pesticides now state:

> The Agency has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

40 C.F.R. 158.640(b)(1); see 40 C.F.R. 158.540; 47 Fed. Reg. 53,192 (1982); 44 Fed. Reg. 27,932, 27,938 (1979) (col. 3). In addition to the requirement that registrants develop and maintain efficacy data, EPA requires the registrant, after a pesticide has been registered, to report incidents of known harm to non-target organisms, such as crops, if the pesticide label does not provide adequate notice of the risk of such harm. 40 C.F.R. 159.184(a)(1)-(3), (b)(3) and (4).

FIFRA's regulatory program encourages federal-state cooperation in regulating pesticides. See *Mortier*, 501 U.S. at 601-602. Section 136v, captioned "Authority of States," sets out key principles of that relationship. See 7 U.S.C. 136v. Section 136v(a) recognizes that, as a general matter, States retain their historic authority to regulate pesticide sale or use, provided that a State does not permit a sale or use that FIFRA, or EPA's implementing regulations, prohibit:

> **(a) In general**
>
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

7 U.S.C. 136v(a). Nevertheless, to ensure a uniform nationwide approach to pesticide labeling, Section 136v(b) provides a specific limitation on a State's authority with respect to the content of pesticide labeling:

> **(b) Uniformity**
>
> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

7 U.S.C. 136v(b). Section 136v(c)(1) further provides that a State shall have the power, subject to various limitations, to allow additional uses of federally registered pesticides within the individual State's borders:

> **(c) Additional uses**
>
> (1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this subchapter and if registration for such use has not previously been denied, disapproved, or cancelled by the Administrator. * * *

7 U.S.C. 136v(c)(1). Section 136v(c)(2) through (4) sets out additional limitations on state-issued registrations. 7 U.S.C. 136v(c)(2)-(4).

In short, Section 136v provides that a State may prohibit the sale or use of any pesticide within its borders. Under specified conditions, a State may also allow a pesticide to be used within its borders for purposes other than those provided in the federal registration. A State may not, however, "impose * * * any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. 136v(b).

B. Factual Background And Proceedings Below

Petitioners are twenty-nine Texas peanut farmers who claim that respondent's Strongarm herbicide product harmed their crops. Pet. App. 1a-2a. Under the Texas Deceptive Trade Practices Act (DTPA), Tex. Bus. & Com. Code Ann. § 17.505(a) (West 2002), plaintiffs seeking judicial relief must give the defendant sixty days' notice before bringing suit. In their notice letters to respondent, petitioners stated that, unless respondent provided compensation, petitioners would bring suit for false advertising, breach of warranty, and fraudulent trade practices under the DTPA. Pet. App. 3a. Before the notice period elapsed, respondent filed suit against petitioners in federal district court. Alleging diversity jurisdiction, respondent sought a declaratory judgment that: (1) all of petitioners' state law claims were preempted by FIFRA; (2) petitioners' remedies were limited to the purchase price of Strongarm because of a paragraph titled "Limitation of Remedies" on the Strongarm label; and (3) petitioners' warranty claims were barred by a "Warranty Disclaimer" paragraph on the label. Petitioners filed counterclaims alleging negligence, breach of implied and express warranties, fraud in the inducement, defective design, estoppel, and waiver. *Ibid.*

The district court granted summary judgment for respondent. Pet. App. 21a-31a. The court ruled that FIFRA preempted petitioners' negligence and warranty claims

because those claims, at bottom, challenged the statements that respondent placed on the Strongarm label. *Id.* at 25a-26a, 30a. The court also held that FIFRA preempted petitioners' fraud claims because those claims were based on alleged statements of respondent's employees and distributors that merely repeated information appearing on the Strongarm label. *Id.* at 27a-28a. Finally, the district court ruled that petitioners' implied warranty claims and petitioners' claims based on alleged oral statements of respondent's employees and distributors that went beyond the label statements were barred by the express disclaimers that respondent placed on the Strongarm label. *Id.* at 26a-27a, 28a-30a.

The court of appeals affirmed. The court first rejected contentions that it lacked subject matter jurisdiction because the claims of some of the petitioners did not meet the amount-in-controversy requirement of 28 U.S.C. 1332(a). Pet. App. 3a-5a. The court of appeals next rejected the argument that the district court abused its discretion by not abstaining from exercising jurisdiction in favor of a state court action brought by petitioners. *Id.* at 4a-5a, 8a.[1]

The court of appeals then turned to the question of federal preemption. The court concluded that this case turns on whether Section 136v(b) of FIFRA, which expressly preempts "any requirements for labeling or packaging in addition to or different from those required" by FIFRA, 7 U.S.C. 136v(b), expressly preempts petitioners' state law claims. Pet. App. 9a-11a. The court specifically rejected petitioners' arguments that "state labeling requirements related to product effectiveness are not within the scope of FIFRA's express preemption clause," *id.* at 11a, and that the particular claims at issue here are not subject to express preemption because they "are not sufficiently related to the

[1] Petitioners do not seek this Court's review of those issues.

content of the Strongarm label," *ibid.* See *id.* at 12a-15a, 15a-19a.

The court rejected petitioners' contention that FIFRA does not preempt product efficacy claims, as opposed to product safety claims. Section 136v(b) expressly preempts "any requirement for labeling," without reference to the subject matter of the labeling requirement, that is "in addition to or different from" what FIFRA requires. Pet. App. 12a-13a. The court specifically noted that "FIFRA's text does not define the scope of FIFRA's preemption clause to be a function of existing EPA regulations." *Id.* at 13a. The court was not persuaded to the contrary by petitioners' citation of *American Cyanamid Co.* v. *Geye*, 79 S.W.3d 21 (Tex. 2002), cert. denied, 123 S. Ct. 2637 (2003), in which the Texas Supreme Court ruled that FIFRA does not preempt certain state law claims respecting crop damage because EPA does not generally evaluate product efficacy. Pet. App. 14a. The court of appeals explained:

> We find *Geye* unhelpful because it did not address the principal issue: whether the scope of FIFRA's express preemption clause includes product effectiveness claims which relate to product labeling. *Geye* holds only that the specific Texas state-law claims for crop damage did not present a problem of conflict preemption under the applicable EPA regulations. In other words, *Geye* proceeds from the assumption that the claims at issue did not relate to product labeling and that FIFRA's express preemption clause did not apply.

Ibid. The court reasoned that Section 136v(b) expressly preempts any state court action that would result in imposing a labeling requirement "in addition to or different from" (7 U.S.C. 136v(b)) a product label that received EPA approval under FIFRA, regardless of whether EPA evaluated product efficacy. Pet. App. 14a-15a.

The court of appeals next considered whether Section 136v(b) preempted the specific claims at issue by examining "whether a judgment against [respondent] would cause it to need to alter the Strongarm label." Pet. App. 16a. See *id.* at 15a-19a. The court concluded that Section 136v(b) preempted petitioners' breach of warranty and fraud-related claims because those claims were predicated on alleged "off label" representations that did not differ in "any material manner" from the Strongarm label. *Id.* at 16a-17a. Imposing liability would, as a practical matter, force respondent to alter its label. *Ibid.* The court concluded that Section 136v(b) preempted petitioners' defective design and negligence claims because each was "a disguised claim for failure to warn" that, if successful, would similarly force respondent to change its label. *Id.* at 18a-19a.

DISCUSSION

The court of appeals correctly ruled that FIFRA expressly preempts petitioners' state law claims alleging that respondent's herbicide damaged their crops. The court properly recognized that Section 136v(b) preempts state law causes of action that would subject a pesticide to labeling requirements "in addition to or different from" the FIFRA-required label. The court evaluated petitioners' specific claims and concluded that each of those claims, if successful, would require respondent to change the contents of its FIFRA-required label.

FIFRA's preemption requirements have generated a substantial amount of litigation. Contrary to petitioners' contentions, however, generally the courts have developed a consistent and coherent approach to resolving preemption claims. This case does not present any square conflict of fundamental importance requiring this Court's review. To the contrary, this case turns largely on the characteristics of petitioners' particular state law claims, which present the

very threat to uniform labeling requirements that led Congress to include an express preemption provision within FIFRA. Those claims, if successful, would require respondent, who obtained a product label by complying with FIFRA's requirements, to change its label to avoid future liability.

A. FIFRA Preempts Petitioners' State-Law Damages Claims

The court of appeals "has addressed the scope of § 136v(b) many times." Pet. App. 10a (citing *Hart* v. *Bayer Corp.*, 199 F.3d 239 (5th Cir. 2000); *Andrus* v. *Agrevo USA Co.*, 178 F.3d 395 (5th Cir. 1999); *MacDonald* v. *Monsanto*, 27 F.3d 1021 (5th Cir. 1994)). Its past decisions have recognized that "FIFRA does not completely preempt all state or local regulation of pesticides," and "FIFRA does not preempt common law that is unconcerned with herbicide labeling," but "FIFRA preempts state laws that either directly or indirectly impose different labeling requirements." *Id.* at 10a-11a. The court noted that it is "well-established that [Section 136v(b)'s] term 'any requirements' encompasses both positive state enactments as well as common-law causes of action." *Id.* at 11a n.8.

The court of appeals explained that petitioners sought to distinguish their state-law claims for judicial relief on the ground that "product effectiveness claims, even those that impose a labeling requirement, are not within the scope of FIFRA's express preemption clause." Pet. App. 12a. The court correctly rejected that distinction. Section 136v(b) expressly preempts "any requirements for labeling" that are "in addition or different from" those that FIFRA imposes. 7 U.S.C. 136v(b). It therefore preempts inconsistent labeling requirements, whether imposed through state legislation, state agency rules, or a state court's articulation of common law standards of care. Under Section 136v(b)'s plain text,

EPA's decision not to require manufacturers to submit efficacy information as part of the registration process is not relevant to the scope of FIFRA's express preemption.

The court of appeals' conclusion that Section 136v(b) generally preempts label-related state tort actions rests on this Court's decision in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992), which held that provisions of the Public Health Cigarette Smoking Act of 1969, 15 U.S.C. 1331 *et seq.* proscribing the imposition of any "requirement or prohibition * * * under State law" (see *Cipollone*, 505 U.S. at 515), encompasses not only state statutes and regulations, but also legal duties applied in common-law tort actions. Pet. App. 12a & n.11; see, *e.g.*, *Taylor AG Indus.* v. *Pure-Gro*, 54 F.3d 555, 559 (9th Cir. 1995) ("There is no notable difference between the language in the 1969 Cigarette Act [preempting state common-law tort actions based on label claims] and the language in FIFRA.").

The court's conclusion finds further support in this Court's decision in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996). The Court ruled in *Medtronic* that the Food and Drug Administration's (FDA's) approval of a pacemaker under the Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539 (21 U.S.C. 301 *et seq.*), did not, under the particular circumstances presented, preempt a state-law action alleging that the pacemaker was improperly designed. Five Justices in that case recognized, however, that the MDA's provisions prohibiting the States from establishing any inconsistent "requirement" that "relates to the safety or effectiveness of the device," 21 U.S.C. 360k(a)(2), could preempt state-law damage suits. See 518 U.S. at 504 (Breyer, J., concurring in part); *id.* at 510-512 (O'Connor, J., concurring in part and dissenting in part).

The court of appeals correctly adhered to *Cipollone* and *Medtronic* in concluding that a Texas state court's application of a legal standard in a state-law damages action

may "impose" "requirements for labeling" (7 U.S.C. 136v(b)). In this Court, petitioners do not take issue with the court of appeals' conclusion that the state law claims at issue here would impose such requirements insofar as they would compel respondents to change the label that they obtained through the FIFRA approval process. See Pet. 28-29 (noting, without disputing, the court of appeals' characterization of "each of the claims as label-related and as 'inducing' the manufacturer to change its label or product"). Thus, the only question is whether Section 136v(b)'s express preemption of state-law damage actions that impose labeling requirements excludes damage actions based on product efficacy.

Section 136v(b)'s unqualified text does not exempt from preemption state-law damages actions based on product efficacy. Petitioners nevertheless urged the court of appeals to create such an exemption on the basis of the Texas Supreme Court's decision in *American Cyanamid Co.* v. *Geye*, *supra*, which also involved a dispute over whether FIFRA preempted state law claims challenging an herbicide's efficacy. The Texas Supreme Court ruled:

> Simply put, the EPA does not regulate herbicide labels regarding how well a product works, and this includes if the product actually injures the crops its was intended to assist. Because of the EPA's choice not to regulate, and therefore because there are no labeling or packaging requirements regarding crop damage imposed under FIFRA, we conclude that state common-law claims about area crop damage are not preempted.

79 S.W.3d at 23. The Texas Supreme Court misunderstood EPA's perspective and practices on the subject of product

efficacy.[2] But setting that error to one side, the court of appeals correctly concluded that the Texas Supreme Court gave insufficient attention to the plain language of Section 136v(b), which expressly states the scope of FIFRA's preemption. Pet. App. 14a.

The court of appeals correctly concluded that EPA's general practice of not independently evaluating product efficacy data is irrelevant to Section 136v(b)'s express preemption inquiry. Congress's 1978 Amendments to FIFRA relieved EPA of any obligation to require registrants to submit efficacy data, but it did not relieve registrants of their obligation to submit accurate labeling for approval in the registration process, 7 U.S.C. 136a(c)(5)(B) (including accurate directions for use, see 40 C.F.R. 156.10(i)), or immunize registrants from FIFRA's penalties for false or misleading labeling, 7 U.S.C. 136j(a)(E); see 40 C.F.R. 156.10(a)(5). The 1978 Amendments also left unchanged the plain terms of Section 136v(b), which prohibit a State from imposing "any requirements" that are "in addition to or different from" the FIFRA requirements. 7 U.S.C. 136v(b).[3]

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[2] Contrary to the Texas Supreme Court's premise in *Geye*, EPA has not abandoned all regulation of product efficacy. EPA continues to require manufacturers to develop and maintain data supporting their efficacy claims. 40 C.F.R. 158.640(b)(1); 40 C.F.R. 158.540. Manufacturers must provide EPA with this data if the agency so requests. *Ibid.* Manufacturers must also report to EPA when they learn that their products have harmed non-target organisms such as crops or persons, if the label does not provide adequate notice of the risk of such harm. 40 C.F.R. 159.184(a)(1). Generally, EPA does not independently evaluate a registrant's product efficacy claims pertaining to agricultural pesticides. For some agricultural products, however, EPA continues to take efficacy into account, albeit in a circumscribed manner, in the registration process. See note 5, *infra*.

[3] Petitioners also rely on EPA Pesticide Regulation Notice (PR) 96-4 (Pet. 4, 11), but that guidance document does not purport to resolve the question at issue here. That document makes clear that, under the

In short, notwithstanding the 1978 Amendments, Section 136v(b) continues to preempt any state-imposed requirements that would add to or subtract from the label for which the registrant obtains approval through the FIFRA registration process. 7 U.S.C. 136v(b). Section 136v(b)'s proscription continues to prohibit a State from requiring the registrant to change the directions for use or to include additional or different product efficacy statements on the label, regardless of whether or not EPA evaluates product efficacy claims in the registration process.

B. The Court Of Appeals' Decision Does Not Give Rise To A Conflict Warranting This Court's Review

Petitioners urge this Court to grant review on the assertion that the many federal and state court decisions addressing FIFRA preemption have created a "jurisprudential mare's nest." Pet. 3, 12. To the contrary, the decision in this case is consistent with a large and generally consistent body of authority holding that FIFRA preempts state-law causes of action, like the claims at issue here, that would require a registrant who has received EPA approval of its

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general registration procedures addressed in that notice, EPA had waived review of the efficacy of agricultural pesticides in the registration process. See PR 96-4 (June 3, 1996) <http://www.epa.gov/opppmsd1/PR_Notices/pr96-4.html>. Accordingly, EPA explained, some courts in FIFRA preemption cases had erred in basing their decisions on the erroneous "premise that, in approving labels for agricultural pesticides, EPA examines, or at least has the obligation to examine, the efficacy of the pesticide and related issues such as the potential for the pesticide to cause property damage." *Ibid.* But PR 96-4 did not express a view on the proper interpretation of the text of FIFRA's preemption provision, nor did it set forth EPA's views regarding the extent to which FIFRA preempts causes of action predicated on the inaccuracy or insufficiency of efficacy claims in an EPA-approved label. *Ibid.* See Letter from Jonathan Z. Cannon, General Counsel, EPA, to Douglas T. Nelson, General Counsel, American Crop Protection Ass'n (Nov. 14, 1996). PR 96-4 is therefore irrelevant to this case.

label under FIFRA to change that label to avoid future liability. Petitioners have constructed elaborate characterizations of the reasoning of the various decisions (Pet. 19-27), but those constructions, whether accurate or not, overlook that the federal and state courts have held, with near uniformity, that FIFRA preempts the types of state law claims that petitioners present in this case.[4]

Petitioners suggest a conflict of authority based primarily on the tension between the court of appeals' decision in this case and the Texas Supreme Court's decision in *Geye*. As *Geye* itself acknowledges, the Texas Supreme Court had previously ruled, in the context of a personal injury suit, that "FIFRA preempts all common law tort suits against manufacturers of EPA-registered pesticides which are based solely upon claims relating directly or indirectly to labeling." 79 S.W.3d at 29 (quoting *Quest Chem. Corp.* v. *Elam*, 898 S.W.2d 819, 820 (Tex. 1995)). The Texas Supreme Court's decision in *Geye*, however, created an exception in the case of state-law claims based on product efficacy. *Ibid.*

Petitioners' alleged conflict accordingly rests on the relatively narrow issue of whether Section 136v(b) preserves from preemption, sub silentio, state-law causes of action that

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[4] As respondent points out (Br. in Opp. 7, 15-16 n.13), nine federal courts of appeals have held that FIFRA expressly preempts state-law based claims that challenge a product's label. See, *e.g.*, Pet. App. 10a-11a; *Grenier* v. *Vermont Log Bldgs. Inc.*, 96 F.3d 559 (1st Cir. 1996); *Hawkins* v. *Leslie's Pool Mart, Inc.*, 184 F.3d 244 (3d Cir. 1999); *Lowe* v. *Sporicidin Int'l*, 47 F.3d 124 (4th Cir. 1995); *Kuiper* v. *American Cyanamid Co.*, 131 F.3d 656 (7th Cir. 1997), cert. denied, 523 U.S. 1137 (1998); *Netland* v. *Hess & Clark Inc.*, 284 F.3d 895 (8th Cir.), cert. denied 537 U.S. 949 (2002); *Nathan Kimmel, Inc.* v. *DowElanco*, 275 F.3d 1199 (9th Cir. 2002); *Arkansas-Platte & Gulf P'ship* v. *Van Waters & Rogers, Inc.*, 959 F.2d 158, aff'd after remand, 981 F.2d 1177 (10th Cir. 1992), cert. denied, 510 U.S. 813 (1993); *Lowe's Home Ctrs., Inc.* v. *Olin Corp.*, 313 F.3d 1307 (11th Cir. 2002). Eighteen state supreme courts have reached the same result. See Br. in Opp. 16-17 n.15

challenge a label's claims respecting the use and effectiveness of the labeled product. The Texas Supreme Court stands alone in carving out such an exception, and it did so through an interlocutory decision in a case in which there is some uncertainty whether the state law claims at issue actually challenged the content of the label. See U.S. Amicus Br. at 9, 11-12, in *American Cyanamid Co.* v. *Geye*, cert. denied, 123 S. Ct. 2637 (2003) (No. 02-367).

It is unclear, moreover, whether the issue deemed so critical to the *Geye* court—a perceived lack of EPA regulation regarding efficacy concerns—is even presented in this case. The Texas Supreme Court predicated its rejection of FIFRA preemption in *Geye* on its view that "Congress authorized the EPA in 1978 to choose not to require the submission of data relating to the 'efficacy' of products." 79 S.W.3d at 25. The court noted that "EPA has chosen not to collect data concerning target area phytotoxicity" and, accordingly, "[w]ith respect to target area phytotoxicity, the EPA makes no review." *Id.* at 25, 29. In this case, however, respondent *did* submit efficacy data to EPA as a prerequisite for EPA's expedited review of Strongarm under 7 U.S.C. 136a(c)(10). See Br. in Opp. 2, 5.[5] Thus, unlike the situation in *Geye*, the registrant submitted efficacy data for EPA review, albeit not in the context of label approval. It is

[5] Congress authorized that review procedure, described in 7 U.S.C. 136a(c)(10), through the 1996 Amendments to FIFRA, which sought to encourage manufacturers to develop pesticides that posed reduced threats to human health and the environment. See Pub. L. No. 104-170, Tit. II, § 250(2), 110 Stat. 1511. EPA set out the review process in PR 97-3 (Sept. 4, 1997), which requires registrants to submit, among other information, "Comparative Performance Data" or efficacy data. EPA requests that information to allow it to determine whether "risk reduction has a reasonable opportunity to be accomplished by adoption of the new pesticide by growers." PR 97-3, Section § VII(G). See <http://www.epa.gov/opppmsd1/PR_Notices/pr97-3.html>.

unclear how the Texas Supreme Court would rule on the preemption issue in these circumstances.[6]

Although the apparent tension between the reasoning of the *Geye* decision and the decision below may necessitate further review at some point, it would be appropriate for this Court to await a case in which the issue is squarely presented. At present, the disagreement between the numerous federal courts of appeals that have recognized that Section 136v(b) broadly preempts state-law causes of action relating to product labels, and a single state supreme court that has recently carved out an exception for product efficacy claims that no other court has followed, does not present a conflict of sufficient breadth, depth, or duration to warrant this Court's review. If the tension between the federal and state appellate courts in Texas ultimately develops into a direct and recurring conflict, this Court's intervention may be called for at that time.

Petitioners also assert (Pet. 19-21, 24-25) that the court of appeals' decision conflicts with one federal court of appeals decision, *Ferebee* v. *Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir.), cert. denied, 469 U.S. 1062 (1984), and two state supreme court decisions, *Sleath* v. *West Mont. Home Health Servs., Inc.*, 16 P.3d 1042, 1051-1053 (Mont. 2000), cert. denied, 534 U.S. 814 (2001), and *Gorton* v. *American Cyanamid Co.*, 533 N.W.2d 746 (Wis. 1995), cert. denied, 516

[6] The position of the United States, as explained in this brief, is that state tort claims based on a lack of efficacy that would, in effect, require the registrant to add to or subtract from the pesticide label in order to avoid liability are preempted regardless of whether EPA receives or reviews efficacy data in a particular case. Under a proper reading of Section 136v(b), the question whether EPA received or reviewed efficacy data is irrelevant to the express preemption inquiry. The United States has identified that question in this case solely for the purpose of explaining why it is not clear that the Texas Supreme Court would have applied its reasoning in *Geye* to the facts presented here.

U.S. 1067 (1996). Those decisions, however, do not present any conflict warranting this Court's review.

The D.C. Circuit's 1984 decision in *Ferebee* does not present a live conflict. The court of appeals stated in that decision that the term "requirements," as used in Section 136v(b), preempts only positive state law and not tort actions. *Ferebee*, 736 F.2d at 1540-1541. The D.C. Circuit decided that case, however, before this Court's decision in *Cipollone*. While the D.C. Circuit has not expressly overruled *Ferebee*, it has since recognized that the term "requirements" is properly understood as encompassing common law actions for damages. In *Waterview Management Co.* v. *FDIC*, 105 F.3d 696 (D.C. Cir. 1997), the court has described *Cipollone* as "explaining that damage actions can be used to enforce state regulations as effectively as other forms of preventive relief and thus damage actions must be preempted where positive enactments are preempted." *Id.* at 699.

The Wisconsin Supreme Court's decision in *Gorton* also does not present a conflict. The state supreme court held that FIFRA did not preempt the plaintiffs' negligent misrepresentation claim in that case, which rested on written and oral representations respecting an herbicide that differed from those on the product label, because that claim did not "challenge the labeling of a manufacturer's product." 533 N.W.2d at 755. See *ibid.* ("All of the statements assuring that [the herbicide] was 'safe' and 'extremely safe' had no relation to the labeling or packaging of the herbicide."). The court's decision in *Gorton* is accordingly distinguishable from this case, in which the court of appeals held that all of petitioners' claims were sufficiently related to the Strongarm label to require preemption. Pet. App. 15-19.

The Montana Supreme Court's decision in *Sleath* does present a conflict insofar as it held, as a general matter, that Section 136v(b) does not preempt state tort actions. *Sleath*,

16 P.3d at 1051-1053. That decision, however, is an anomaly among the large number of federal and state court decisions that have squarely ruled that the term "requirements," as used in Section 136v(b), includes state common law standards of care. See note 4, *supra*. The Montana Supreme Court's ruling was influenced by the United States' filing of two appellate court briefs, in 1999, taking the position that FIFRA does not preempt state-law actions seeking compensation for damages arising from pesticide use. *Sleath*, 16 P.3d at 1047-1048; see U.S. Amicus Br., *Hart* v. *Bayer Corp.*, No. 98-60496 (5th Cir. filed Mar. 1999); U.S. Amicus Br., *Etcheverry* v. *TRI-AG Serv. Inc.*, No. S072524 (Cal. filed Mar. 1999).

As the United States explained in its brief amicus curiae to this Court in *American Cyanamid Co.* v. *Geye*, *supra*, the United States has concluded that the position taken in those lower courts is incorrect. See U.S. Amicus Br. at 17, *American Cyanamid Co.* v. *Geye*, cert. denied, 123 S. Ct. 2637 (2003) (No. 02-367). Because the Montana Supreme Court's anomalous decision rests in part on a position that the United States no longer endorses, that court may wish to reconsider its views. In any event, the conflict between that single state supreme court and a vast body of contrary federal and state judicial decisions has limited practical importance and does not present a matter that requires this Court's resolution at this time.

CONCLUSION

The petition for a writ of certiorari should be denied.
Respectfully submitted.

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IN THE

Supreme Court of the United States

DENNIS BATES, *ET AL.*,

Petitioners,

v.

DOW AGROSCIENCES LLC,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

JOINT APPENDIX

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS (LUBBOCK)

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action
	)	No. 5:01-CV-00331
	)	
DENNIS BATES, [*et al.*],	)	
	)	
Defendants.	)	

CIVIL DOCKET

Filing Date	#	Docket Text
12/21/2001	1	COMPLAINT FOR DECLARATORY RELIEF filed; Filing Fee $150.00 Receipt # 37724 (dws) (Entered: 12/21/2001)
		* * * * *
01/22/2002	5	ORIGINAL ANSWER to Complaint by defendant Dennis Bates, [*et al.*] (Attorney Phil Watkins) (ebl) (Entered: 01/22/2002)
		* * * * *
01/29/2002	33	MOTION by defendant Dennis Bates, [*et al.*] to dismiss plaintiff 's suite [*sic*] for lack of jurisdiction (ebl) (Entered: 01/29/2002)

01/29/2002	34	MEMORANDUM by defendant Dennis Bates, [*et al.*] in support of [33-1] motion to dismiss plaintiff 's suite [*sic*] for lack of jurisdiction (ebl) (Entered: 01/29/2002)

* * * * *

02/14/2002	37	RESPONSE by plaintiff Dow Agrosciences LLC to [33-1] motion to dismiss plaintiff 's suit for lack of jurisdiction (ebl) (Entered: 02/15/2002)
02/14/2002	38	APPENDIX by plaintiff Dow Agrosciences LLC in support of [37-1] motion response (ebl) (Entered: 02/15/2002)
03/12/2002	39	ORDER denying [33-1] motion to dismiss plaintiff 's suit for lack of jurisdiction, improper venue and lack of subject matter jurisdiction. Defendants' Motion to Dismiss Plaintiff 's suit under the Court's discretionary authority to abstain is DENIED. All relief not expressly granted in [*sic*] DENIED. (Signed by Judge Sam R. Cummings) Copies to counsel: 3/12/2002 Page(s) 10 (ebl) (Entered: 03/12/2002)
03/13/2002	40	MOTION by plaintiff Dow Agrosciences LLC for summary judgment on principles of federal pre-emption and the uniform commercial code (ebl) (Entered: 03/13/2002)

03/13/2002	41	MEMORANDUM by plaintiff Dow Agrosciences LLC in support of [40-1] motion for summary judgment (ebl) (Entered: 03/13/2002)
03/13/2002	42	APPENDIX by plaintiff Dow Agrosciences LLC in support of [40-1] motion for summary judgment (ebl) (Entered: 03/13/2002)

* * * * *

03/27/2002	45	UNOPPPOSED MOTION by defendant Dennis Bates, [*et al.*] for leave to file Counterclaims (ebl) (Entered: 03/27/2002)
03/27/2002	46	MEMORANDUM by defendant Dennis Bates, [*et al.*] in support of [45-1] motion for leave to file Counterclaims (ebl) (Entered: 03/27/2002)
03/27/2002	47	ORDER granting [45-1] motion for leave to file Counterclaim (Signed by Judge Sam R. Cummings) Copies to counsel: 3/28/02 Page(s) 2 (ebl) (Entered: 03/28/2002)
04/02/2002	49	RESPONSE (MEMORANDUM) by defendant Dennis Bates, [*et al.*] in opposition to [40-1] motion for summary judgment (ebl) (Entered: 04/02/2002)
04/02/2002	50	APPENDIX by defendant Dennis Bates, [*et al.*] in support of [49-1] opposition response (ebl) (Entered: 04/02/2002)

* * * * *

04/04/2002	52	ADDENDUM TO DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT by defendant Dennis Bates, [*et al.*] (ebl) (Entered: 04/04/2002)
04/11/2002	53	MOTION by defendant Dennis Bates, [*et al.*] to amend [48-1] counter claim (ebl) (Entered: 04/11/2002)
04/15/2002	54	MOTION with memorandum in support by plaintiff Dow Agrosciences LLC to amend, join parties, and extend deadline to join additional party (ebl) (Entered: 04/15/2002)
04/15/2002	55	APPENDIX by plaintiff Dow Agrosciences LLC in support of [54-1] motion to amend, join parties, and extend deadline to join additional party (ebl) (Entered: 04/15/2002)
04/17/2002	56	REPLY BRIEF by plaintiff Dow Agrosciences LLC to response to [40-1] motion for summary judgment (ebl) (Entered: 04/17/2002)
04/19/2002	57	AMENDED REPLY by plaintiff Dow Agrosciences LLC to response to [40-1] motion for summary judgment (ebl) (Entered: 04/19/2002)
04/23/2002	58	ANSWER by counter-defendant Dow Agrosciences LLC to [48-1] counter claim (ebl) (Entered 04/24/2002)

04/25/2002	59	RESPONSE to [54-1] motion to amend, join parties, and extend deadline to join additional party by Robert Tracy Griffiths, Sand Farms, Inc., Comanche Horizon Corporation, and Sheila Gruben (ebl) (Entered: 04/25/2002)
04/25/2002	60	APPENDIX in support of [59-1] motion response (ebl) (Entered: 04/25/2002)
05/01/2002	61	RESPONSE by plaintiff Dow Agrosciences LLC to [53-1] motion to amend [48-1] counter claim (ebl) (Entered 05/01/2002)
05/10/2002	62	REPLY by plaintiff Dow Agrosciences LLC to response to [54-1] motion to amend, join parties, and extend deadline to join additional party, brief in support, and request for expedited ruling (ebl) (Entered: 05/10/2002)
05/10/2002	63	APPENDIX by plaintiff by Dow Agrosciences LLC in support of [62-1] response reply (ebl) (Entered: 05/10/2002)
06/03/2002	64	ORDER granting [40-1] motion for summary judgment (SEE ORDER FOR FURTHER INFORMATION) (Signed by Judge Sam R. Cummings) Copies to counsel: 6/3/02 Page(s) 9 (ebl) (Entered: 06/03/2002)

06/03/2002	65	JUDGMENT; the court declares that the Defendants' available remedies, if any, are limited to those set forth in the Limitations of Remedies section of the federally approved Strongarm label; the Warranty Disclaimer section of the federally approved Strongarm label is valid and enforceable; and the Plaintiff's and the Defendants' rights and obligations are governed by the federally approved Strongarm label and any claims directly or indirectly attacking that federally approved label, and/or the EPA-approved composition of Strongarm, are expressly and impliedly preempted by the Federal Insecticide, fungicide and Rodenticide Act, 7 USC 136 et seq. (Signed by Judge Sam R. Cummings) Copies to counsel: 6/3/02 Page(s): 1 (ebl) (Entered: 06/03/2002)
06/03/2002		Case closed (ebl) (Entered: 06/03/2002)
06/14/2002	66	MOTION by defendants for reconsideration of [65-1] judgment order (klw) Modified on 06/14/2002 (Entered: 06/14/2002)
06/14/2002	67	MEMORANDUM by defendants in support of [66-1] motion for reconsideration of [65-1] judgment order (klw) Modified on 06/14/2002 (Entered: 06/14/2002)

06/14/2002	68	APPENDIX by defendants in support of [66-1] motion for reconsideration of [65-1] judgment order (klw) (Entered: 06/14/2002)
06/17/2002	69	MOTION with memorandum in support by plaintiff Dow Agrosciences LLC to alter or amend [65-1] judgment order, and motion for expedited review (ebl) (Entered: 06/17/2002)
06/17/2002	70	APPENDIX by plaintiff Dow Agrosciences LLC in support of [69-1] motion to alter or amend [65-1] judgment order (ebl) (Entered: 06/17/2002)
06/25/2002	71	RESPONSE by defendant Dennis Bates, [*et al.*] to [69-1] motion to alter or amend [65-1] judgment order (ebl) (Entered: 06/25/2002)
06/25/2002	72	APPENDIX by defendant Dennis Bates, [*et al.*] in support of [71-1] motion response (ebl) (Entered: 06/25/2002)
06/25/2002	73	ORDER denying [69-1] motion to alter or amend [65-1] judgment order (Signed by Judge Sam R. Cummings) Copies to counsel: 6/25/02 Page(s) 1 (ebl) (Entered 06/25/2002)
07/05/2002	74	RESPONSE by plaintiff Dow Agrosciences LLC to [66-1] motion for reconsideration of [65-1] judgment order (bdg) UNFILED PER ORDER SIGNED 07/31/03 DOCUMENT # 75. Modified on 7/31/2003 (bdg,). (Entered: 07/05/2002)

07/05/2002	75	APPENDIX by plaintiff Dow Agrosciences LLC in support of [74-1] motion response (bdg) (Entered: 07/05/2002)
07/08/2002	76	ORDER denying [66-1] motion for reconsideration of [65-1] judgment order (Signed by Judge Sam R. Cummings) Copies to counsel: 7/8/02 Page(s) 2 (egb) (Entered: 07/08/2002)

* * * * *

08/06/2002	78	NOTICE OF APPEAL by defendant Dennis Bates, [*et al.*] re [76-1] order, [65-1] judgment order, [64-1] order, [39-1] order (bdg) (Entered: 08/07/2002)
08/07/2002		Notice of appeal and certified copy of docket to USCA: [78-1] appeal (bdg) (Entered: 08/07/2002)

* * * * *

08/15/2002	Transmitted record on appeal to U.S. Court of Appeals: [78-1] appeal; Consisting of six (6) volumes of record (bdg) (Entered: 08/15/2002)
08/28/2002	USCA Case Number, 02-10908 Re: [78-1] appeal (bdg) (Entered: 08/28/2002)

* * * * *

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff-Appellee,	)	
	)	
v.	)	No. 02-10908
	)	
DENNIS BATES, [*et al.*],	)	
	)	
Defendants-Appellants.	)	

DOCKET ENTRIES

8/16/02	Private civil diversity case docketed. NOA filed by Appellants Dennis Bates, Jimmy Burson, Benny Judah, Tommy Coleman, Richard Cox, Et Al. [02-10908] (cnf)

* * * * *

8/21/02	Record on appeal filed. Vol(s) of Pleadings: 6. [02-10908] (jca)

* * * * *

10/23/02	Appellant's Brief filed by Appellant Dennis Bates, [*et al.*] Copies of brief: 7 # of pages: 61. Word count: 13,966 Disk Provided [Y/N]: y Date of COS: 10/22/02 Sufficient [Y/N]: y. [02-10908] A/Pet's Brief ddl satisfied. E/Res's Brief due on 11/22/02 for Dow Agrosciences LLC. (rsm)
10/23/02	Record excerpts filed by Appellant Dennis Bates, [*et al.*] # of copies: 4 Sufficient [Y/N]: y [02-10908] (rsm)

* * * * *

11/25/02 Appellee's Brief filed by Appellee Dow Agrosciences LLC. Copies of Brief: 7 # of pages: 63. Word count: 13,919 Disk Provided [Y/N]: y Date of COS: 11/22/02 Sufficient [Y/N]: y. [02-10908] E/Res's Brief ddl satisfied. Reply Brief due on 12/9/02 for Dennis Bates, [*et al.*]. (tws)

* * * * *

12/11/02 Reply brief filed by Appellant Dennis Bates, [*et al.*] Copies of Brief: 7 # of pages: 29. Word count: 6,905 Disk Provided [Y/N]: y Date of COS: 12/9/02 Sufficient [Y/N]: y. [02-10908] Reply Brief ddl satisfied. (rsm)

12/23/02 Supplemental authorities (FRAP 28(j)) filed by Appellee Dow Agrosciences LLC [4052438-1]. [02-10908] (rff)

* * * * *

03/12/03 Unopposed motion filed by Burk Denman to be dismissed as appellant [4124803-1] Date of COS: 3/11/03 Sufficient [Y/N]: y [02-10908] (rff)

03/12/03 Letter referencing unopposed motion to dismiss Burk Denman as appellant [4124803-1] filed by Appellee Dow Agrosciences LLC [4124825-1] [02-10908] (rff)

3/19/03 CLERK Order filed granting unopposed motion for partial dismissal of appeal [4124803-1] Involvement terminated for party Burk Denman. Copies to all counsel. [02-10908] (trm)

4/9/03 Supplemental authorities (FRAP 28(j)) filed by Appellant Dennis Bates, [*et al.*] [4154459-1] [02-10908] (pft)

4/10/03 Oral argument heard. Case argued by Sharon E Callaway for Appellant Dennis Bates, [*et al.*], Dean T Barnhard for Appellee Dow Agrosciences LLC [02-10908] (pft)

6/3/03 Supplemental authorities (FRAP 28(j)) filed by Appellee Dow Agrosciences LLC [4209226-1] [02-10908] (rff)

6/11/03 Opinion filed. If Published # of pages: 9 Issue Mandate due on 7/2/03. [02-10908] (kgc)

6/11/03 Judgment entered and filed. [02-10908] (kgc)

6/24/03 Motion filed by Appellant Dennis Bates, [*et al.*] to stay the mandate [4230077-1] Response/ Opposition due on 7/7/03. Date of COS: 6/23/03 Sufficient [Y/N]: y [02-10908] (rff)

* * * * *

7/23/03 COURT Order filed denying appellants' motion to stay mandate [4230077-1] (PEH) Copies to all counsel. [02-10908] (trm)

7/23/03 Mandate issued. Approved BOC Issued (Y/N)?: y [02-10908] Mandate pull date satisfied. (jca)

* * * * *

9/17/03 Supreme Court notice that petition for certiorari was filed on 09/09/03 by Appellant Dennis Bates, [*et al.*] Supct No.: 03-388 [02-10908 (lgl)

6/28/04 Supreme Court order received granting petition certiorari [4890776-1] by Appellant Dennis Bates, [*et al.*] on 6/28/04. [02-10908] (lgl)

7/19/04 Certified record on appeal transmitted to United States Supreme Court. 5th Cir. Vols: 1 DCt. Vols: 15 Supplemental Vols: 1 [02-10908] (trm)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action
	)	No. 5-01CV0331-C
DENNIS BATES, [*et al.*],	)	
	)	
Defendants.	)	

[Filed Dec. 21, 2001]

COMPLAINT FOR DECLARATORY RELIEF

Dow AgroSciences LLC ("Dow AgroSciences"), by its attorneys, hereby brings this action for declaratory relief and alleges as follows:

JURISDICTION AND VENUE

1. This is a civil action over which this Court has original federal subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (a)(1). There is complete diversity of citizenship between the parties and the matter in controversy exceeds the sum or value of seventy-five thousand ($75,000), exclusive of interest or costs, with respect to each individual Defendant.

2. Venue in this district is proper pursuant to 28 U.S.C. § 1391(a)(1) in that the majority of the defendants reside in this judicial district in the State of Texas and all defendants reside in the State of Texas.

3. Venue in this district is proper pursuant to 28 U.S.C. § 1391(a)(2) because a substantial part of the events or omissions giving rise to the claims herein

occurred in this district and because a substantial part of the property that is the subject matter of this action is situated in this district.

4. This Court also has supplemental jurisdiction over the dispute between Dow AgroSciences and the defendants pursuant to 28 U.S.C. § 1367(a) in that the defendants' claims are part of the same case or controversy as those of the other defendants and arise from the same central core of operative facts.

5. This Court has personal jurisdiction over each defendant pursuant to 2 Tex. Civ. Prac. & Rem. Code Ann. § 17.042.

PARTIES

6. Dow AgroSciences is a Delaware limited liability company with its principal place of business in Marion County, Indiana. Dow AgroSciences LLC was originally created as DowElanco, an Indiana general partnership, on October 31, 1989. DowElanco converted to a limited liability company on July 1, 1997 (DowElanco LLC) and changed its name to Dow AgroSciences effective January 1, 1998. Dow AgroSciences is a citizen of both Delaware and Indiana as provided by 28 U.S.C. § 1332(c)(1).

7. Defendants are a group of individual peanut crop growers who are citizens of the state of Texas residing in Baylor, Brisco, Brown, Collingsworth, Dawson, Eastland, Stephens, Erath, Fisher, Gaines, Hall, Hamilton, Haskell, Lamb, and Yoakum counties ("Defendants").

DECLARATORY JUDGMENT

8. This case involves an actual controversy, within the jurisdiction of this Court, and a judicial declaration is necessary regarding the rights and other legal relations between the plaintiff Dow AgroSciences and the Defendants, as set out below. Therefore, the relief

requested by Dow AgroSciences is specifically authorized by 28 U.S.C. §§ 2201 and 2202 and Fed. R. Civ. P. 57.

STATEMENT OF FACTS

9. Dow AgroSciences is, among other things, a manufacturer of pest management and biotechnology products. In the Spring of 2000, Dow AgroSciences introduced a new product, Strongarm*, which was used as a preemergence herbicide to control certain weeds in peanuts. Strongarm was introduced in the Southwest of the United States, including within this district.

10. The active ingredient in Strongarm is diclosulam.

11. Strongarm is registered with the United States Environmental Protection Agency pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y. As part of the initial registration process under FIFRA for the Strongarm herbicide, Dow AgroSciences submitted all scientific data and information required by the EPA. The EPA determined that the data submitted by Dow AgroSciences to the EPA in support of the initial registration of Strongarm herbicide was in compliance with the requirements of FIFRA and registered Strongarm and assigned the registration number 62719-288 on March 8, 2000.

12. As part of the initial registration process for the Strongarm herbicide, Dow AgroSciences received from the EPA a stamped and accepted product label.

13. At all times relevant hereto, Dow AgroSciences has sold the Strongarm herbicide with labels that were accepted by the EPA and affixed to the product at the time of the sale.

---

* Trademark of Dow AgroSciences LLC.

14. The growing season in the Southwest in 2000 was challenging. Yields from peanut crops in Texas and Oklahoma were significantly lower than in previous years due to a severe mid-season drought and late-season rain and snow, which made harvest difficult. Water quality and quantity, as well as other cultural management practices, were also questionable.

15. Upon information and belief, near the end of 2000 counsel for various peanut growers were openly soliciting clients for a mass suit against Dow AgroSciences based on the allegation that the lower-than expected yields from peanut crops in Texas and Oklahoma were caused by and attributable solely to the individual growers' use of Strongarm.

16. Seventy-five individual peanut grower's represented by counsel have sent claim demand letters to Dow AgroSciences. Seventy are named as defendants in this action and in an action filed concurrently with this one in the United States District Court for the Western District of Oklahoma, collectively. Each of the individual Defendants' claims exceeds the $75,000 amount in controversy for purposes of jurisdiction pursuant to 28 U.S.C. § 1332 which includes specific demands for consequential and incidental damages, treble damages, and attorneys' fees and expenses. Combined, their claim demands excluding expenses and attorneys' fees total approximately $40,000,000.

17. The Defendants' contend that Strongarm was "highly toxic" and failed to control weeds in their peanut crops. The Defendants also contend that Dow AgroSciences misrepresented the product as being "of a particular standard, quality, and grade" and that these misrepresentations constituted false, misleading and deceptive acts and practices. Further, the Defendants allege false advertising, breach of warranty and statutory claims for alleged deceptive and fraudulent trade

practices. The Defendants have demanded payment from Dow AgroSciences for certain damages, including consequential and incidental damages, treble damages and attorneys' fees and expenses.

18. The federally-approved Strongarm label sets forth "Terms and Conditions of Use," "Warranty Disclaimer," "Inherent Risks," and "Limitations of Remedies."

19. Dow AgroSciences contends that upon the individual Defendants' purchase, retention and use of Strongarm, contracts between the individual Defendants and Dow AgroSciences were created, with the text of the federally-approved Strongarm label supplying the terms of those contracts and defining the parties' respective rights and liabilities.

20. Due to the nature of the claims made against Dow AgroSciences, it is clear that the individual Defendants refuse to acknowledge the existence of such contracts and that they further refuse to acknowledge that the text of the federally-approved Strongarm label defines the parties' respective rights, obligations and liabilities upon Strongarm's failure to perform as Defendants claim they expected.

21. The Terms and Conditions of Use section provides that the purchaser should return the unopened package of Strongarm at once for a full refund if the Warranty Disclaimer, Inherent Risks of Use, and Limitations of Remedies are unacceptable to the purchaser. The Terms and Conditions also provide that use of the product constitutes acceptance of the terms of the label.

22. The Warranty Disclaimer provides "that th[e] product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label . . . . The Disclaimer also provides: "Dow AgroSciences makes NO OTHER EXPRESS OR IMPLIED WARRANTY OR

IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY."

23. The Inherent Risks of Use section provides that risks such as crop injury are assumed by the buyer where abnormal conditions, e.g., drought, exist.

24. The Limitation of Remedies section provides as follows:

> The exclusive remedy for losses or damages resulting from the use of this product (including claims based on contract, negligence, strict liability, or other legal theories), shall be limited to, at Dow AgroSciences' election, one of the following:
>
> 1. Refund of purchase price paid by buyer or user for product bought, or
>
> 2. Replacement of amount of product used.
>
> Dow AgroSciences shall not be liable for losses or damages resulting from handling or use of this product unless Dow AgroSciences is promptly notified of such loss or damage in writing. In no case shall Dow AgroSciences be liable for consequential damages or incidental damages or losses.
>
> The terms of the Warranty Disclaimer above and this Limitation of Remedies cannot be varied by any written or verbal statements or agreements. No employee or sales agent of Dow AgroSciences or the seller is authorized to vary or exceed the terms of the Warranty Disclaimer of this Limitation of Remedies in any manner.

25. A controversy exists between Dow AgroSciences and the Defendants regarding the enforceability of these provisions on the federally-approved Strongarm label and the viability of Defendants' claims against Dow AgroSciences.

COUNT I

26. Dow AgroSciences incorporates by reference paragraphs 1 through 25 of its Complaint as if fully set forth herein.

27. Affixed to each container of Strongarm purchased by Defendants was a federally-approved label which contained a "Limitation of Remedies."

28. A limitation of remedies provision, such as the one included on the Strongarm label, is valid and enforceable pursuant to Tex. Bus. & Com. Code Ann. § 2.719.

29. Defendants have asserted a right to recover damages from Dow AgroSciences in an amount which exceeds that permitted by the Limitation of Remedies section in the federally-approved Strongarm label.

30. A justiciable controversy exists between Dow AgroSciences and Defendants regarding the rights and other legal relations of the parties with respect to the remedies available to the Defendants such that a declaration is necessary pursuant to 28 U.S.C. §§ 2201 and 2202.

31. Dow AgroSciences is entitled to a declaration that Defendants' available remedies, if any, are limited to those set forth in the Limitation of Remedies section of the federally-approved Strongarm label.

COUNT II

32. Dow AgroSciences incorporates by reference paragraphs 1 through 31 of its Complaint as if fully set forth herein.

33. Affixed to each container of Strongarm purchased by Defendants was a federally-approved label which contained a "Warranty Disclaimer."

34. A provision, such as the one included on the federally-approved Strongarm label, disclaiming express or implied warranties is valid and enforceable pursuant to Tex. Bus. & Com. Code Ann.§ 2.316.

35. Defendants have asserted a right to bring claims for breach of express and implied warranties against Dow AgroSciences.

36. A justiciable controversy exists between Dow AgroSciences and Defendants regarding the rights and other legal relations of the parties with respect to the enforceability of the Warranty Disclaimer such that a declaration is necessary pursuant to 28 U.S.C. §§ 2201 and 2202.

37. Dow AgroSciences is entitled to a declaration that the Warranty Disclaimer section of the label is valid and enforceable.

COUNT III

38. Dow AgroSciences incorporates by reference the allegations contained in paragraphs 1 - 37.

39. Under the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 136-136y, all herbicides sold or distributed in the United States must be registered with the Administrator of the Environmental Protection Agency. The EPA also regulates both the design and content of the label for a registered herbicide. The final printed labeling for a herbicide must be submitted and accepted by the Administrator before registration, and it is unlawful to sell an unregistered herbicide.

40. In determining the rights and legal relations of Dow AgroSciences and Defendants under the contract terms contained in the federally-approved Strongarm product label, this Court will be required to examine principles of federal preemption, which originate from the Supremacy Clause of the United States Constitution (U.S.

Const., Art. VI, cl. 2), and issues of federal law and congressional intent, which originate from FIFRA.

41. The responsibility of the EPA to regulate the labeling and registration of herbicide products is inherently federal in character, and the availability of state law remedies with respect to unexpected consequences of use of a federally registered herbicide are governed by and limited by federal law.

42. Defendants have challenged the adequacy and sufficiency of Dow AgroSciences's federally-approved Strongarm product label by alleging claims for damages against Dow AgroSciences under theories of fraud, false advertising, misrepresentation, negligence in design, testing and marketing, breach of express and implied warranty and statutory claims for alleged deceptive and fraudulent trade practices.

43. At all times relevant hereto, Dow AgroSciences has sold the Strongarm herbicide with labels that were accepted by the EPA and affixed to the product at the time of the sale.

44. FIFRA contains an express preemption clause that provides that a state "shall not impose or continue in effect any requirements for labeling and packaging in addition to or different from those required under [FIFRA]." 7 U.S.C. § 136v(b). This provision expressly preempts plaintiffs' direct and indirect challenges to the adequacy and sufficiency of any EPA-approved herbicide labeling or packaging.

45. Defendants' claims are also impliedly preempted by federal law because they (1) conflict with FIFRA's regulatory scheme and (2) directly conflict with the express authority given to registrants – such as Dow AgroSciences – to "distribute or sell a registered product with the composition, packaging and labeling currently approved by the Agency." 40 C.F.R. § 152.130(a).

46. A justiciable controversy exists between Dow AgroSciences and Defendants regarding the rights and other legal relations of the parties with respect to federal preemption of the Defendants' claims such that a declaration is necessary pursuant to 28 U.S.C. §§ 2201 and 2202.

PRAYER FOR RELIEF

For the foregoing reasons, Dow AgroSciences respectfully requests that the Court:

1. Declare that the Defendants' available remedies, if any, are limited to those set forth in the Limitation of Remedies section of the federally-approved Strongarm label; and

2. Declare that the Warranty Disclaimer section of the federally-approved Strongarm label is valid and enforceable;

3. Declare that the Plaintiffs and the Defendants' rights and obligations are governed by the federally-approved Strongarm label and any claims directly or indirectly attacking that federally-approved label, and/or the EPA approved composition of Strongarm, are expressly and implied preempted by federal statute and all regulations promulgated thereunder; and

4. Award any other relief that the Court deems just and proper.

JURY DEMAND

Plaintiff Dow AgroSciences LLC respectfully demands a jury trial on all claims and issues.

Dated: December 21, 2001

Respectfully submitted,

THOMPSON & KNIGHT L.L.P.

By: /s/ Frank L. Hill, by
Fernando M. Bustos (by permission)
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ATTORNEYS FOR PLAINTIFFS
DOW AGROSCIENCES LLC

Of Counsel:
BARNES & THORNBURG
Dean T. Barnhard
Joseph G. Eaton
11 South Meridian St.
Indianapolis, Indiana 46204
Telephone: (317) 236-1313
Fax: (317) 231-7433

ATTORNEYS FOR PLAINTIFF
DOW AGROSCIENCES LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action
	)	No. 5-01CV0331-C
DENNIS BATES, [*et al.*],	)	
	)	
Defendants.	)	

[Filed Jan. 22, 2002]

DEFENDANTS' ORIGINAL ANSWER

TO THE HONORABLE JUDGE OF SAID COURT:

Defendants Dennis Bates, Jimmy Burson, Benny Judah, d/b/a Clearwater Farms, Tommy Coleman, Richard Cox, Wayne Davis, Burk Denman, Neil Friessen, Jake Forese, Thomas Fuston, Arthur Galvan, d/b/a G-5 Partnership, Greg Hughes, Sandra and Karl Don Hughes, d/b/a JH Cattle Co., Rudy Klassen, Ronnie Love, Kevin Mathis, Brad Palmer, Kirk Parrish, d/b/a K-L Farms, Jerry Parrish, Joevelyn Patterson and Donald Gruben, Stacey Price, Benny Judah, d/b/a Progressive Farms, Morris Rushing, d/b/a Pea-Dot Farms, Billy Shannon, Floyd Stokes, Craig West, Frenchie Lee Wheeler file this Original Answer to Plaintiff's Complaint for Declaratory Relief.

ADMISSIONS AND DENIALS

1. Defendants deny the allegations in Paragraph 1.
2. Defendants deny the allegations in Paragraph 2.
3. Defendants deny the allegations in Paragraph 3.

4. Defendants deny the allegations in Paragraph 4.
5. Defendants deny the allegations in Paragraph 5.
6. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegation in Paragraph 6.
7. Defendants deny the allegations in Paragraph 7.
8. Defendants deny the allegations in Paragraph 8.
9. Defendants admit the allegations in Paragraph 9.
10. Defendants admit the allegations in Paragraph 10.
11. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegation in Paragraph 11.
12. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegation in Paragraph 12.
13. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegation in Paragraph 13.
14. Defendants deny the allegation in Paragraph 14.
15 Defendants deny the allegation in Paragraph 15.
16. Defendants deny the allegations in Paragraph 16.
17. Defendants admit the allegations in Paragraph 17.
18. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegation in Paragraph 18.
19. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegation in Paragraph 19.
20. Defendants admit the allegations in Paragraph 20.
21. Defendants deny the allegations in Paragraph 21.

22. Defendants admit the allegations in Paragraph 22.

23. Defendants admit the allegations in Paragraph 23.

24. Defendants admit the allegations in Paragraph 24.

25. Defendants admit that a controversy exists between Dow Agrosciences and Defendants regarding the enforceability of the warranty disclaimer and limitation of remedies but denies the remaining allegations in Paragraph 25.

26. Defendants admit the allegations in Paragraph 26.

27. Defendants deny the allegations in Paragraph 27.

28. Defendants deny the allegations in Paragraph 28.

29. Defendants admit that they have asserted a right to recover damages against Dow Agrosciences. Defendants deny the remaining allegations in Paragraph 29.

30. Defendants deny the allegations in Paragraph 30.

31. Defendants deny the allegations in Paragraph 31.

32. Defendants admit the allegations in Paragraph 32.

33. Defendants deny the allegations in Paragraph 33.

34. Defendants deny the allegations in Paragraph 34.

35. Defendants admit the allegations in Paragraph 35.

36. Defendants deny the allegations in Paragraph 36.

37. Defendants deny the allegations in Paragraph 37.

38. Defendants admit the allegations in Paragraph 38.

39. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegation in Paragraph 39.

40. Defendants deny the allegations in Paragraph 40.

41. Defendants admit the allegations in Paragraph 41.

42. Defendants admit the allegations in Paragraph 42.

43. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegation in Paragraph 43.

44. Defendants deny the allegations in Paragraph 44.

45. Defendants deny the allegations in Paragraph 45.

46. Defendants deny the allegations in Paragraph 46.

Plaintiff has sued Defendants Tommy Coleman, Burk Denman, and Floyd Stokes in the wrong capacity because each Defendant does not have the capacity to defend as an individual.

AFFIRMATIVE DEFENSES

Even if Plaintiff proves the allegations in its complaint, by its conduct Plaintiff is estopped to deny liability to the Defendants; is estopped to deny the Limitation of Remedies provision in its label and has waived the Warranty Disclaimer and Limitation of Remedies provision in its label. The Plaintiff, by and through its representatives, fraudulently induced the Defendants to use Strongarm in their peanut fields in the year 2000 growing season and further represented to the Defendants that if they would grow their peanut crop to maturity the delay in growth due to stunting would resolve itself and would result in a normal crop and, if it did not, Dow Agrosciences would pay each Defendant for their crop losses including all incidental and consequential losses.

PRAYER

For each of the above and foregoing reasons, Defendants ask the court to render judgment that the Plaintiff take nothing and dismiss Plaintiff's suit with prejudice, award costs against Plaintiff and award Defendants their reasonable and necessary attorneys' fees,

costs and expenses together with such other and further relief to which each Defendant is justly entitled, either at law or in equity.

Respectfully submitted,

PHIL WATKINS, P.C.

One Riverwalk Place, Suite 1750
700 N. St. Mary's Street
San Antonio, Texas 78205
Telephone: (210) 225-6666
Telecopier: (210) 225-2300

BY: /s/ Phil Watkins
PHIL WATKINS
State Bar No. 20927400

ATTORNEYS FOR DEFENDANT

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action
	)	No. 5-01CV0331-C
DENNIS BATES, [*et al.*],	)	
	)	
Defendants.	)	

[Filed Feb. 14, 2002]

PLAINTIFF DOW AGROSCIENCES LLC'S RESPONSE TO DEFENDANTS' MOTION TO DISMISS AND BRIEF IN SUPPORT

Respectfully submitted:

Frank L. Hill
State Bar No. 09631500
Thompson & Knight
1200 San Jacinto Center
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Fax: (512) 496-6180
Attorney for Plaintiff

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Lubbock, Texas 79493
Telephone: (806) 796-7300
Telecopier: (806) 796-7365
Attorney for Plaintiff

[Text Omitted, Exhibits Excerpted]

* * * * *

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action
	)	No. 5-01CV0331-C
DENNIS BATES, [*et al.*],	)	
	)	
Defendants.	)	

AFFIDAVIT OF JOSEPH R. ALBERTS

STATE OF INDIANA §
COUNTY OF MARION §

BEFORE ME, the undersigned authority, on this day personally appeared JOSEPH R. ALBERTS, who, being by me duly sworn on his oath, deposed as follows:

"My name is Joseph R. Alberts. I reside in Hamilton County, Indiana. I work in Marion County, Indiana. I am over the age of 18, of sound mind, have never been convicted of any crime involving moral turpitude, and have personal knowledge of the following facts. I am fully competent to make this Affidavit.

I am a Senior Litigation Attorney for Dow AgroSciences LLC. I am employed as an attorney by and for Dow AgroSciences LLC. The documents included in pages 003 through 166 of the Appendix to Plaintiff Dow AgroSciences LLC's Response to Defendants' Motion to Dismiss are true and correct copies of letters that I received from Phil Watkins, attorney for Defendants in

this case. Pages 003 through 166 of Plaintiff's Appendix are incorporated by reference within this Affidavit."

Further, Affiant sayeth not.

/s/ Joseph R. Alberts
DATED: February 12, 2002 JOSPEH R. ALBERTS

[Notary Omitted]

[LETTERS OMITTED]

WATKINS, CICHOWSKI & GONZALEZ, P.C.

[Letterhead Names/Address Omitted]

[Stamp Omitted]

October 30, 2001

Mr. Joseph R. Alberts
Senior Litigation Counsel
Law Department
Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268-1054

Via CM-RRR # 7001 0360 0003 6428 0077

RE: *Strongarm* Herbicide*

Dear Mr. Alberts:

As you know this law firm has been retained to represent Mr. Burke Denman, with respect to the claim he has against Dow Agrosciences, LLC, concerning his purchase and use of Strongarm*.

Mr. Denman purchased the Strongarm* from his local retailer in the Spring of 2000. The Strongarm* was represented by Dow as having the characteristics and ingredients of a good herbicide when in fact the product was highly toxic which caused damage to Mr. Denman's peanuts and continues to cause damage to his land. In addition, the Strongarm* was represented by the Dow representative as being of a particular standard, quality, and grade when in fact it did not have any of these qualities.

My client's complaint is that the conduct of Dow AgroSciences constitutes false, misleading and deceptive acts and practices in violation of §17.46(b)(5) and (7) of the Texas Deceptive Trade Practices-Consumer Protection Act.

Based upon the information now available to us and for the purpose of this notice letter, we estimate Mr.

Denman's damage is at least $37,992.50 for his 59.30 acres of peanuts he had in production in 2000. Attached hereto are Mr. Denman's documents verifying his damages.

Mr. Denman reserves the right to adjust the amounts of his damages to conform to the information and additional evidence that may be available at a later date. He believes that the above damage claims are correct, to the best of his information and belief.

In addition, Mr. Denman has incurred reasonable and necessary attorney fees and expenses in the pursuit of his claims as stated in this letter. The amount of attorney fees and expenses incurred as of the date of this letter are at least $10,000.00. This amount will increase as time passes.

The purpose of this letter is to encourage Dow AgroSciences to resolve Mr. Denman's claims in a fair and equitable manner without the need of further expense. In the event Dow fails to take advantage of this settlement offer, we will have no other alternative but to recommend to our client that a lawsuit be filed and prosecuted to its conclusion under the Texas Deceptive Trade Practices-Consumer Protection Act.

If you are interested in resolving this matter, please contact me in writing within (60) sixty days of your receipt of this letter.

Very truly yours,

WATKINS, ClCHOWSKI &
GONZALEZ, P.C.
/s/ Michael Miller
Michael Miller

MM:mgr
cc:
Mr. Burke Denman

[LETTERS OMITTED]

WATKINS, CICHOWSKI & GONZALEZ, P.C.

[Letterhead Names/Address Omitted]

[Stamp Omitted]

September 27, 2001

Mr. Joseph R. Alberts
Senior Litigation Counsel
Law Department
Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268-1054

Via CM-RRR # 7001 0360 0003 6428 0312

RE: *Strongarm* Herbicide*

Dear Mr. Alberts:

As you know this law firm has been retained to represent Mr. Dennis Bates, with respect to the claim he has against Dow AgroSciences, LLC, concerning his purchase and use of Strongarm*.

Mr. Bates purchased the Strongarm* from his local retailer in the Spring of 2000. The Strongarm* was represented by Dow as having the characteristics and ingredients of a good herbicide when in fact the product was highly toxic which caused damage to Mr. Bates' peanuts and continues to cause damage to his land. In addition, the Strongarm* was represented by the Dow representative as being of a particular standard, quality, and grade when in fact it did not have any of these qualities.

My client's complaint is that the conduct of Dow AgroSciences constitutes false, misleading and deceptive acts and practices in violation of §17.46(b)(5) and (7) of the Texas Deceptive Trade Practices-Consumer Protection Act.

Based upon the information now available to us and for the purpose of this notice letter, we estimate Mr. Bates'

damage is at least $100,327.50 for his 67 acres of peanuts he had in production in 2000. Attached hereto are Mr. Bates' documents verifying his damages.

Mr. Bates reserves the right to adjust the amounts of his damages to conform to the information and additional evidence that may be available at a later date. He believes that the above damage claims are correct, to the best of his information and belief.

In addition, Mr. Bates has incurred reasonable and necessary attorney fees and expenses in the pursuit of his claims as stated in this letter. The amount of attorney fees and expenses incurred as of the date of this letter are at least $10,000.00. This amount will increase as time passes.

The purpose of this letter is to encourage Dow AgroSciences to resolve Mr. Bates' claims in a fair and equitable manner without the need of further expense. In the event Dow fails to take advantage of this settlement offer, we will have no other alternative but to recommend to our client that a lawsuit be filed and prosecuted to its conclusion under the Texas Deceptive Trade Practices-Consumer Protection Act.

If you are interested in resolving this matter, please contact me in writing within (60) sixty days of your receipt of this letter.

Very truly yours,

WATKINS, CICHOWSKI & GONZALEZ, P.C.

/s/ Michael Miller
Michael Miller

MM:mgr
cc:
Mr. Dennis Bates

WATKINS, CICHOWSKI & GONZALEZ, P.C.

[Letterhead Names/Address Omitted]

[Stamp Omitted]

September 20, 2001

Mr. Joseph R. Alberts
Senior Litigation Counsel
Law Department
Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268-1054

Via CM-RRR # 7001 0360 0003 6428 0336

RE: *Strongarm* Herbicide*

Dear Mr. Alberts:

As you know this law firm has been retained to represent Mr. Jimmy Burson, with respect to the claim he has against Dow AgroSciences, LLC, concerning his purchase and use of Strongarm*.

Mr. Burson purchased the Strongarm* from his local retailer in the Spring of 2000. The Strongarm* was represented by Dow as having the characteristics and ingredients of a good herbicide when in fact the product was highly toxic which caused damage to Mr. Burson's peanuts and continues to cause damage to his land. In addition, the Strongarm* was represented by the Dow representative as being of a particular standard, quality, and grade when in fact it did not have any of these qualities.

My client's complaint is that the conduct of Dow AgroSciences constitutes false, misleading and deceptive acts and practices in violation of §17.46 (b)(5) and (7) of the Texas Deceptive Trade Practices-Consumer Protection Act.

Based upon the information now available to us and for the purpose of this notice letter, we estimate Mr.

Burson's damage is at least $67,620.00 for his 65 acres of peanuts he had in production in 2000. Attached hereto are Mr. Burson's documents verifying his damages.

Mr. Burson reserves the right to adjust the amounts of his damages to conform to the information and additional evidence that may be available at a later date. He believes that the above damage claims are correct, to the best of his information and belief.

In addition, Mr. Burson has incurred reasonable and necessary attorney fees and expenses in the pursuit of his claims as stated in this letter. The amount of attorney fees and expenses incurred as of the date of this letter are at least $10,000.00. This amount will increase as time passes.

The purpose of this letter is to encourage Dow AgroSciences to resolve Mr. Burson's claims in a fair and equitable manner without the need of further expense. In the event Dow fails to take advantage of this settlement offer, we will have no other alternative but to recommend to our client that a lawsuit be filed and prosecuted to its conclusion under the Texas Deceptive Trade Practices-Consumer Protection Act.

If you are interested in resolving this matter, please contact me in writing within (60) sixty days of your receipt of this letter.

Very truly yours,

WATIKINS, CICHOWSKI & GONZALEZ, P.C.

/s/ Michael Miller
Michael Miller

MM:mgr
cc:
Mr. Jimmy Burson

[LETTERS OMITTED]

APPENDIX

Summary of Motion to Dismiss Defendants' Residence by County And Federal Judicial District

Defendants' establish the county of residence for each Defendant, in their Motion to Dismiss. Their argument, in relevant part, reads:

a. Defendant Dennis Bates resides in Brown County, Texas situated in the San Angelo ~~Division of~~ the **Northern District of Texas**.

b. Jimmy Burson resides in Haskell County, Texas situated in the Abilene Division of the **Northern District of Texas**.

c. Benny Judah, d/b/a Clearwater Farms resides in Lubbock County, Texas [which is within the **Northern District of Texas**].

d. Tommy Coleman is not a proper party but resides in Collingsworth County, Texas situated in the Amarillo Division of the **Northern District of Texas**.

e. Richard Cox resides in Baylor County, Texas situated in the Wichita Falls Division of the **Northern District of Texas**.

f. Wayne Davis resides in Yoakum County, Texas [which is within the **Northern District of Texas**].

g. Burk Denman is not a proper party as he is deceased. The personal representative of his estate resides in Comanche County, Texas situated in the Fort Worth Division of the **Northern District of Texas**.

h. Neil Friessen resides in Gaines County, Texas [which is within the **Northern District of Texas**].

i. Jake Forese resides in Gaines County, Texas [which is within the **Northern District of Texas**].

j. Thomas Fuston resides in Hall County, Texas situated in the Amarillo Division of the **Northern District of Texas**.

k. Arthur Galvan, d/b/a G-5 Partnership, resides in Yoakum County, Texas [which is within the **Northern District of Texas**].

l. Greg Hughes resides in Gaines County, Texas [which is within the **Northern District of Texas**].

m. Sandra and Karl Don Hughes, d/b/a JH Cattle Co., reside in Gaines County, Texas [which is within the **Northern District of Texas**].

n. Rudy Klassen resides in Gaines County, Texas [which is within the **Northern District of Texas**].

o. Ronnie Love resides in Eastland County, Texas situated in the Abilene Division of the **Northern District of Texas**.

p. Kevin Mathis resides in Haskell County, Texas situated in the Abilene Division of the **Northern District of Texas**.

q. Brad Palmer resides in Yoakum County, Texas [which is within the **Northern District of Texas**].

r. Kirk Parrish, d/b/a K-L Farms, resides in Yoakum County, Texas [which is within the **Northern District of Texas**].

s. Jerry Parrish resides in Yoakum County, Texas [which is within the **Northern District of Texas**].

t. JoEvelyn Patterson resides in Haskell County, Texas situated in the Abilene Division of the **Northern District of Texas**.

u. Donald Gruben resides in Haskell County, Texas situated in the Abilene Division of the **Northern District of Texas**.

v. Stacey Price resides in Hall County, Texas situated in the Amarillo Division of the **Northern District of Texas**.

w. Benny Judah, d/b/a Progressive Farms, resides in Lubbock County, Texas [which is within the **Northern District of Texas**].

x. Morris Rushing, d/b/a/ Pea-Cot Farms, resides in Yoakum County, Texas [which is within the **Northern District of Texas**].

y. Billy Shannon resides in Hall County, Texas situated in the Amarillo Division of the **Northern District of Texas.**

z. Floyd Stokes is not a proper party but, resides in Erath County, Texas situated in the Forth Worth Division of the **Northern District of Texas**.

aa. Craig West resides in Lamb County, Texas [which is within the **Northern District of Texas**].

bb. Frenchie Lee Wheeler resides in Brown County, Texas situated in the San Angelo Division of the **Northern District of Texas**.

Motion to Dismiss at 4-7.

Appendix

Summary of demands made by Defendants (the letters by which these demands were transmitted are included, *supra*, in this Appendix)

- Dennis Bates: $100,327.50
  Letter dated 9/27/01.
- Jimmy Burson: $67,620.00; "In addition, Mr. Burson has incurred reasonable and necessary attorney fees . . . [of] at least $10,000.00."

Thus, the total for Mr. Burson's claims exceed $77,620.00.
Letter dated 9/20/01.

- Clearwater Farms: $385,397.50
  (Benny Judah)
  Letter dated 9/20/01.
- Tommy Coleman: $301,217.50
  Letter dated 10/04/01.
- Wayne Davis: $267,267.50
  Letter dated 9/20/01.
- Neil Freissen: $444,810.00
  Letter dated 10/30/01.
- Jake Forese: $530,080.00
  Letter dated 9/27/01.
- Thomas Fuston: $584,290.00
  Letter dated 10/04/01.
- G-5 Partnership: $320,080.00
  (Arthur Galvan)
  Letter dated 9/20/01.
- Arthur Galvan: $613,247.50
  Letter dated 9/20/01.

- Greg Hughes: $177,570.00
  Letter dated 9/25/01.
- JH Cattle Co. $485,702.50
  (Sandra and
  Karl Don Hughes)
  Letter dated 9/25/01.
- Rudy Klassen: $95,135.00
  Letter dated 10/04/01.
- Ronnie Love: $395,142.50
  Letter dated 9/07/01.
- Kevin Mathis: $203,245.00
  Letter dated 10/30/01.
- Brad Palmer: $182,005.00
  Letter dated 8/28/01.
- K-L Farms: $145,062.50
  (Kirk Parrish)
  Letter dated 9/25/01.
- Jerry Parrish: $267,155.00
  Letter dated 9/25/01.
- JoEvelyn Patterson: $182,750.00
  (& Donald Gruben)
  Letter dated 9/20/01.
- Stacy Price: $278,730.00
  Letter dated 10/30/01.
- Progressive Farms: $328,832.50
  (Benny Judah)
  Letter dated 9/20/01.
- Pea-Cot Farms: $314,335.00
  (Morris Rushing)
  Letter dated 11/16/01.
- Billy Shannon: $215,132.50
  Letter dated 10/30/01.

- Floyd Stokes: $19,775,000.00
  Letter dated 9/04/01.

- Craig West: $125,035.00
  Letter dated 10/30/01.

The remaining three Defendants made the following claims:

- Frenchie Lee Wheeler: $18,242.50; "In addition, Mr. Wheeler has incurred reasonable and necessary attorney fees and expenses in the pursuit of his claims as stated in this letter. The amount of attorneys fees and expenses incurred as of the date of this letter are at least $10,000.00. This amount will increase as time passes. The purpose of this letter is to encourage Dow AgroSciences to resolve Mr. Cox's claims in a fair and equitable manner without the need of further expense. In the event Dow fails to take advantage of this settlement offer, we will have no other alternative but to recommend to our client that a lawsuit be filed and prosecuted to its conclusion under the Texas Deceptive Trade Practices-Consumer Protection Act."

Letter dated 9/27/01. Of course, the Defendants' DTPA claim contemplates treble damages as provided by that statute. *E.g., Love v. Dow AgroSciences*, Plaintiff's Original Petition, Count X(f); Tex. Bus. & Com. Code §17.50(b)(1)(Vernon 2000). Such trebling constitutes part of the amount in controversy. *Villegas*, 242 F.3d at 284; *Fairmont Travel*, 75 F. Supp. 2d at 668. Thus, the total for this Defendant is $84,727.50.

- Richard Cox: $33,227.50; "In addition, Mr. Cox has incurred reasonable and necessary

attorney fees and expenses in the pursuit of his claims as stated in this letter. The amount of attorneys fees and expenses incurred as of the date of this letter are at least $10,000.00. This amount will increase as time passes. The purpose of this letter is to encourage Dow AgroSciences to resolve Mr. Cox's claims in a fair and equitable manner without the need of further expense. In the event Dow fails to take advantage of this settlement offer, we will have no other alternative but to recommend to our client that a lawsuit be filed and prosecuted to its conclusion under the Texas Deceptive Trade Practices-Consumer Protection Act."

Letter dated 9/04/01. Of course, the DTPA claim contemplates treble damages as provided by that statute. *E.g., Love v. Dow AgroSciences*, Plaintiff's Original Petition, Count X(f); Tex. Bus. & Com. Code Ann. § 17.50(b)(1)(Vernon 2000). Such trebling constitutes part of the amount in controversy. *Villegas*, 242 F.3d at 284; *Fairmont Travel*, 75 F. Supp. 2d at 668. Thus, the total for this Defendant is $129.682.50.

- Burk Denman: $37,992.50; "In addition, Mr. Denman has incurred reasonable and necessary attorney fees and expenses in the pursuit of his claims as stated in this letter. The amount of attorneys fees and expenses incurred as of the date of this letter are at least $10,000.00. This amount will increase as time passes. The purpose of this letter is to encourage Dow AgroSciences to resolve Mr. Cox's claims in a fair and equitable manner without the need of

> further expense. In the event Dow fails to take advantage of this settlement offer, we will have no other alternative but to recommend to our client that a lawsuit be filed and prosecuted to its conclusion under the Texas Deceptive Trade Practices-Consumer Protection Act."

Letter dated 10/30/01. Of course, the DTPA claim contemplates treble damages as provided by that statute. *Eg., Love v. Dow AgroSciences*, Plaintiff's Original Petition, Count X(f); Tex. Bus. & Com. Code Ann. §17.50(b)(1)(Vernon 2000). Such trebling constitutes part of the amount in controversy. *Villegas*, 242 F.3d at 284; *Fairmont Travel*, 75 F. Supp. 2d at 668. Thus, the total for this Defendant is $129,682.50.

---

[1] Even if the Fifth Circuit did not recognize punitive damages as appropriately included in a determination of the amount in controversy, the appropriate remedy would be to dismiss only those three individual defendants, and not as to the remaining twenty-two.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

[Stamp omitted]

DOW AGROSCIENCES, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No.
	)	5:01-CV-331-C
DENNIS BATES, *et al.*,	)	
	)	
Defendants.	)	

[Filed Mar. 12, 2002]

ORDER

On this day the Court considered Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction, Improper Venue, and Failure to State a Claim filed January 29, 2002. Plaintiff filed a Response to Defendant's Motion to Dismiss on February 14, 2002. No Reply was filed. After considering all relevant arguments and evidence, the Court **DENIES** Defendants' Motions to Dismiss.

I.

BACKGROUND

Plaintiff, Dow AgroSciences, manufactures pest management and biotechnology products. Plaintiff introduced Strongarm in the spring of 2000. Strongarm is used as a preemergence herbicide to control certain weeds in peanuts. Plaintiff began receiving demand letters from individual peanut growers (Defendants) contending that

Strongarm was "highly toxic" and failed to control the weeds in their peanut crops. The Defendants also contended that Plaintiff misrepresented the product and that the misrepresentations constituted false, misleading, and deceptive acts and practices. In addition, Defendants alleged false advertising, breach of warranty, and statutory claims for alleged deceptive and fraudulent trade practices. Defendants' demand letters demanded payment from Plaintiff for certain damages, including consequential and incidental damages, treble damages, and attorneys' fees and expenses. On December 21, 2001, Plaintiff brought suit seeking declaratory judgment.

II.

STANDARD

Rule 12(b)(1) Subject Matter Jurisdiction

Motions filed under Rule 12(b)(1) of the Federal Rules of Civil Procedure allow a party to challenge the subject matter jurisdiction of the district court to hear a case. FED. R. CIV. P. 12(b)(1). Lack of subject matter jurisdiction may be found in any one of three instances: (1) the complaint alone; (2) the complaint supplemented by undisputed facts evidenced in the record; or (3) the complaint supplemented by undisputed facts plus the court's resolution of disputed facts. *Barrera-Montenegro v. United States*, 74 F.3d 657, 659 (5th Cir. 1996).

The burden of proof for a Rule 12(b)(1) motion to dismiss is on the party asserting jurisdiction. *McDaniel v. United States*, 899 F. Supp. 305, 307 (E.D. Tex. 1995). Accordingly, the plaintiff constantly bears the burden of proof that jurisdiction does in fact exist. *Menchaca v. Chrysler Credit Corp.*, 613 F.2d 507, 511 (5th Cir. 1980).

When a Rule 12(b)(1) motion is filed in conjunction with other Rule 12 motions, the court should consider the Rule 12(b)(1) jurisdictional attack before addressing any

attack on the merits. *Hitt v. City of Pasadena*, 561 F.2d 606, 608 (5th Cir. 1977) (per curiam). This requirement prevents a court without jurisdiction from prematurely dismissing a case with prejudice. *Id.* The court's dismissal of a plaintiff's case because the court lacks subject matter jurisdiction is not a determination on the merits and does not prevent the plaintiff from pursuing a claim in a court that does have proper jurisdiction. *Id.*

In examining a Rule 12(b)(1) motion, the district court is empowered to consider matters of fact which may be in dispute. *Williamson v. Tucker*, 645 F.2d 404, 413 (1981). Ultimately, a motion to dismiss for lack of subject matter jurisdiction should be granted only if it appears certain that the plaintiff cannot prove any set of facts in support of his claim that would entitle plaintiff to relief. *Home Builders Ass'n of Miss., Inc. v. City of Madison, Miss.*, 143 F.3d 1006, 1010 (5th Cir. 1998).

Rule 12(b)(3) Improper Venue

Motions under Federal Rule of Civil Procedure 12(b)(3) are used to raise the defense of improper venue, which challenges the plaintiff's forum selection. If improper venue is not challenged in the answer or pre-answer stage of the case, the challenge is waived. FED. R. CIV. P. 12(h)(1); *see also Albany Ins. Co. v. Almacenadora Somex, S.A.*, 5 F.3d 907, 909 (5th Cir. 1993). "If a proper objection is made to venue, it is for the court to determine whether the objection is well taken. The court, rather than a jury, decides contested fact issues relating to the venue question." 15 C. WRIGHT, A. MILLER & E. COOPER, FEDERAL PRACTICE AND PROCEDURE § 3826 (2d ed. 1986). The plaintiff has the burden of establishing that venue is proper in the district selected. *Nelson v. International Paint Co., Inc.*, 734 F.2d 1084, 1089 (5th Cir. 1984).

Section 1391(a) of Title 28 of the United States Code states:

> A civil action wherein jurisdiction is founded only on diversity of citizenship may, except as otherwise provided by law, be brought only in (1) a judicial district where any defendant resides, if all defendants reside in the same State, (2) a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, or a substantial part of property that is the subject of the action is situated, or (3) a judicial district in which any defendant is subject to personal jurisdiction at the time the action is commenced, if there is no district in which the action may otherwise be brought.

If a court determines that venue is improper under § 1391, the court may dismiss the case, or, in the interest of justice, transfer the case to any district or division in which it could have been brought. 28 U.S.C. § 1406(a).

Rule 12(b)(6) Failure to State a Claim

Motions to dismiss for failure to state a claim are appropriate when a defendant attacks the complaint because it fails to state a legally cognizable claim. FED. R. CIV. P. 12(b)(6). The test for determining the sufficiency of a complaint under Rule 12(b)(6) was set out by the United States Supreme Court as follows: "[A] complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). *See also, Grisham v. United States*, 103 F.3d 24, 25-26 (5th Cir. 1997).

Subsumed within the rigorous standard of the Conley test is the requirement that the plaintiff's complaint be stated with enough clarity to enable a court or an opposing party to determine whether a claim is sufficiently alleged. *Elliott v. Foufas*, 867 F.2d 877, 880 (5th Cir. 1989). Further, "the plaintiffs complaint is to be construed in a

light most favorable to the plaintiff, and the allegations contained therein are to be taken as true." *Oppenheimer v. Prudential Sec., Inc.*, 94 F.3d 189, 194 (5th Cir. 1996). This is consistent with the well-established policy that the plaintiff be given every opportunity to state a claim. *Hitt*, 561 F.2d at 608. In other words, a motion to dismiss an action for failure to state a claim "admits the facts alleged in the complaint, but challenges plaintiff's rights to relief based upon those facts." *Tel-Phonic Servs., Inc. v. TBS Int'l, Inc.*, 975 F.2d 1134, 1137 (5th Cir. 1992). Finally, when considering a Rule 12(b)(6) motion to dismiss for failure to state a claim, the district court must examine the complaint to determine whether the allegations provide relief on any possible theory. *Cinel v. Connick*, 15 F.3d 1338, 1341 (5th Cir. 1994).

III.

DISCUSSION

Rule 12(b)(1) Subject Matter Jurisdiction

The Declaratory Judgment Act is not an independent basis for federal jurisdiction. Before declaratory relief can be granted, federal subject matter jurisdiction requirements must be satisfied. *Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 671 (1950). Actions for declaratory relief must, therefore, be between parties of diverse citizenship or "arise under" federal law. Moreover, the Declaratory Judgment Act authorizes declaratory relief only in a "case of actual controversy." 28 U.S.C. § 2201. This requirement is the same as the "case or controversy" requirement of Article III of the United States Constitution. *Middle South Energy, Inc. v. City of New Orleans*, 800 F.2d 488, 490 (5th Cir. 1986).

Defendants have raised the issue that Plaintiff has failed to plead a substantive jurisdictional basis for this Court to entertain a dispute filed under the Declaratory Judgment Act. Plaintiff alleges that there is federal

subject matter jurisdiction pursuant to 28 U.S.C. §§ 1332(a)(1). Defendants claim that this Court does not have subject matter jurisdiction because some of the Defendants' claims do not exceed $75,000. Plaintiff directs the Court to Defendants' demand letters wherein every letter except three demands more than $75,000.

Regarding the three Defendants whose actual monetary figures did not exceed $75,000, the additional demands for attorneys' fees and punitive damages exalts the total amount in controversy over $75,000. *See U.S. Fire Ins. Co. v. Villegas*, 242 F.3d 279, 283 (5th Cir. 2001). Plaintiff, relying on Defendants' demand letters, had a good faith belief that the amount in controversy was met.

Plaintiff does not make conclusory statements that the amount in controversy exceeds $75,000. Because Defendants did not submit any evidence refuting Plaintiff 's amount in controversy, this Court looks only to the face of the pleadings to determine the sufficiency of the amount in controversy. *Paterson v. Weinberger*, 644 F.2d 521, 526 (5th Cir. 1981); *Bradley v. U.S. Dept. of Commerce, PTO*, 598 F.Supp. 38, 39 (N.D. Tex. 1984). This Court is satisfied that the amount in controversy exceeds $75,000.

Defendants also contend that there is no case or controversy between Plaintiff and Defendants. Plaintiff claims that an actual case or controversy does exist between the parties.

Plaintiff bases this claim on the numerous demand letters received from Defendants. The demand letters stated in part, "[I]n the event Dow [Plaintiff] fails to take advantage of this settlement offer, we will have no other alternative but to recommend to our client [Defendants] that a lawsuit will be filed and prosecuted." As a general rule, an actual case or controversy exists where a "substantial controversy of sufficient immediacy and reality [exists] between parties having adverse legal

interests." *Middle South Energy Inc. v. City of New Orleans*, 800 F.2d 488, 490 (5th Cir. 1986). The threat of litigation, if specific and concrete, can establish a case or controversy upon which declaratory judgment can be based. *Orix Credit Alliance, Inc. v. Wolfe*, 212 F.3d 891, 897 (5th Cir. 2000). The Court is satisfied that an actual case or controversy exists between Plaintiff and Defendants.

Rule 12(b)(3) Improper Venue

Venue relates to the locality in which a lawsuit may be properly brought. *Minnesota Min. & Mfg. Co. v. Eco Chem, Inc.*, 757 F.2d 1256, 1264 (Fed. Cir. 1985), *citing Neirbo v. Bethlehem Shipbuilding Corp.*, 308 U.S. 165, 167-68 (1939). The purpose of a venue requirement is to protect defendants from being forced to defend lawsuits in a court remote from their residence or from where the acts underlying the controversy occurred. *Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 84 F.3d 1408, 1410 (Fed. Cir. 1996).

Defendants claim that venue is improper in this Court and that this Court should dismiss or transfer this case to the Abilene Division, Amarillo Division, Ft. Worth Division, San Angelo Division, and the Wichita Falls Division of the Northern District of Texas. Plaintiff alleges venue is proper in the Lubbock Division pursuant to 28 U.S.C. § 1391(a)(1). Section 1391(a)(1) provides:

> (a) A civil action wherein jurisdiction is founded only on diversity of citizenship may, except as otherwise provided by law, be brought only in (1) a judicial district where any defendant resides, if all defendants reside in the same State, ...

Section 1391(a)(1) speaks in terms of districts and not divisions. It appears to the Court that Defendants have confused the two terms. Venue is proper in the Lubbock Division because every named defendant resides in the

Northern District of Texas; Section 1391 (a)(1) requires that any one defendant reside in the district when all of the defendants reside in the state. Moreover, Defendants' argument that more than half of the Defendants reside outside the Lubbock Division—in the Abilene, Amarillo, Ft. Worth, San Angelo, and Wichita Falls Divisions of the Northern District & Texas—establishes the propriety of venue in the Northern District. If venue is proper in the Abilene, Amarillo, Ft. Worth, San Angelo, or Wichita Falls Division, it is *ipso facto* proper in the Lubbock Division.

Discretionary Abstention

The Declaratory Judgment Act states that courts may declare rights; however, they may decline to do so. *Brillhart v. Excess Ins. Co. of Am.*, 316 US 491, 494 (1942). It is well settled in the Fifth Circuit that a district court has discretion over whether to decide or dismiss a declaratory judgment action. *Granite State Ins. Co. v. Tandy Corp.*, 986 F.2d 94 (5th Cir. 1992). Defendants urge this Court to exercise its discretion and to decline jurisdiction over this matter.

The relevant factors which this Court must consider include 1) whether there is a pending state action in which all of the matters in controversy may be fully litigated; 2) whether the plaintiff filed suit in anticipation of a lawsuit filed by the defendant; 3) whether the plaintiff engaged in forum shopping in bringing the suit; 4) whether possible inequities in allowing the declaratory plaintiff to gain precedence in time or to change forums exist; 5) whether the federal court is a convenient forum for the parties and witnesses; and 6) whether retaining the lawsuit in federal court would serve the purposes of judicial economy. *Travelers Ins. Co. v. Louisiana Farm Bureau Federation*, 996 F.2d 774, 778 (5th Cir. 1993).

First, there are currently numerous pending state court proceedings; however, Plaintiff filed this suit more than a month before any of the pending state court suits

were filed. *See Rowan Companies, Inc. v. Ainsworth*, 5 F.Supp.2d 420, 422 (5th Cir. 1998). Moreover, this factor is not dispositive and Fifth Circuit precedent requires the Court to examine several factors and does not restrict the inquiry to only this one factor. *See Travelers*, 996 F.2d at 777. The second and third factors support a denial of abstention: Plaintiff neither brought this suit in anticipation nor did Plaintiff forum shop in bringing this suit. Plaintiff brought this suit in an effort to avoid multiple lawsuits in numerous state courts; Plaintiff had already received seventy-five demand letters from individual Defendants before filing suit. Additionally, Plaintiff was not forum shopping when it chose to file suit in Lubbock. Defendants' argument that Plaintiff was forum shopping because all of the Defendants do not reside in the Lubbock Division must fall since all of the Defendants do reside in the Northern District of Texas and this suit is properly before this Court.

With regard to the fourth and fifth factors, Defendants have failed to point to any inequities that this forum would pose other than the fact that all Defendants do not reside in Lubbock. This argument, however, fails for the reasons previously discussed. In addition, Lubbock provides a convenient forum for the parties and witnesses when the location of all the Defendants, as well as the Plaintiff, is considered. The final factor, judicial economy, weighs heavily in support of retention of this case. Plaintiff brought this suit in this Court to avoid a multiplicity of suits in various state courts throughout Texas. Multiple lawsuits in various courtrooms could result in differing and conflicting decisions as well as a waste of judicial time.

Plaintiff 's goal in bringing this suit to avoid multiple lawsuits is consistent with the purpose of the Declaratory Judgment Act. *Travelers*, 996 F.2d 774, 776. After addressing the applicable law in light of the facts of this case, it is clear that abstention is inappropriate.

Rule 12(b)(6) Failure to State a Claim

Defendants argue that this suit should be dismissed because Plaintiff has failed to state a claim. However, after examination, the Court finds that Plaintiff has stated a claim for which relief may be granted.

IV.

CONCLUSION

For the reasons previously discussed, Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction, Improper Venue and Lack of Subject Matter Jurisdiction is **DENIED**. Defendants' Motion to Dismiss Plaintiff's suit under the Court's discretionary authority to abstain is **DENIED**. All relief not expressly granted is **DENIED**.

SO ORDERED this 12TH day of March, 2002.

/s/ Sam R. Cummings
SAM R. CUMMINGS
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

[Stamp omitted]

DOW AGROSCIENCES, LLC,	)	
	)	
Plaintiff,	)	
v.	)	Civil Action No.
	)	5-01-CV-331-C
DENNIS BATES, *et al.*,	)	
	)	
Defendants.	)	

[Filed Mar. 13, 2002]

PLAINTIFF DOW AGROSCIENCES LLC'S BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT ON PRINCIPLES OF FEDERAL PRE-EMPTION AND THE UNIFORM COMMERCIAL CODE

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ATTORNEYS FOR
PLAINTIFF

[Text Omitted, Exhibits Excerpted]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action
	)	No. 5-01CV0331-C
DENNIS BATES, [*et al.*],	)	
	)	
Defendants.	)	

AFFIDAVIT OF RAFAEL HERRERA

Rafael Herrera, being duly sworn, deposes and says:

1. My name is Rafael Herrera. I am an adult, over the age of 21 years and I am competent to testify as to all matters stated herein.

2. I am employed by Dow AgroSciences LLC ("Dow AgroSciences") as a Registration manager for, among others, Strongarm• herbicide. I am familiar with the facts and circumstances discussed herein, which are based upon personal knowledge and upon review of business records of Dow AgroSciences.

3. As Registration Manager for Dow AgroSciences, I am responsible for all matters concerning the federal registration of Strongarm herbicide pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"). I am familiar with the regulations promulgated and enforced pursuant to FIFRA by the Environmental Protection Agency ("EPA") and other applicable federal laws and regulations.

• Trademark of Dow AgroSciences LLC

4. My responsibilities as Registration manager include assuring that Dow AgroSciences fully complies with applicable EPA requirements and regulations concerning the federal registration of Strongarm herbicide.

5. The EPA accepted the product label for Strongarm herbicide on March 8, 2000, and assigned registration number 62719-288. Attached hereto as **Exhibit A** is a true and accurate stamped copy of the EPA's acceptance and the accepted product label. The acceptance was conditioned upon Dow AgroSciences submitting the data listed therein, which Dow AgroSciences thereafter submitted.

6. At all times relevant hereto, Dow AgroSciences sold Strongarm herbicide only with EPA-accepted labels affixed to the product at the time of the sale. A true and accurate copy of the product label in effect during the time period relevant to the claims involved in the above-referenced lawsuit bears Label Code D02-044-003 and is attached hereto as **Exhibit B**.

7. By its acceptance of the product label for Strongarm herbicide, the EPA determined that the data submitted by Dow AgroSciences in support of its registration complied with all FIFRA requirements.

FURTHER, the affiance sayeth not.

/s/ Rafael Herrera

Dated: 03/01/2002 Rafael Herrera

[Notary Omitted]

EXHIBIT A

[Seal Omitted]

U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
401 "M" St., S.W.
Washington, D.C. 20460

Notice of Pesticide:
X Registration
_ Reregistration
Under FIFRA, as amended

EPA Reg. Number: 62719-288
Date of Issuance: Mar 8, 2000
Term of Issuance: Conditional
Name of Pesticide Product: Strongarm

Name and Address of Registrant (include ZIP Code):
Dow AgroSciences
9330 Zionsville Road
Indianapolis, IN 46268-1054

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5), 3(g), or 4 when the Agency requires all registrants of similar products to submit such data.

2. Submit the following data and information by February 28, 2001:

a. A new ames mutagenicity test conducted at adequate dose levels.

b. Additional information concerning the metabolism study for poultry and eggs and the rotational crop study. The storage time between sampling and analysis for poultry, eggs, and rotational crops must be reported. If the storage time was longer than 6 months, adequate data concerning the stability of residues during the storage period between collection and final analysis must be provided.

c. Analysis of plant metabolism or field trial samples of peanut and soybean for 2,6-dichloroaniline (2,6-DCA) using a validated method at the parts per billion level. The storage time between sampling and analysis for 2,6-DCA must be reported. If the storage time was longer than 6 months, adequate data concerning the stability of 2,6-DCA residues during the storage period between collection and final analysis must be provided.

Signature of Approving Official: Date:

[SIGNATURE OMITTED] March 8, 2000

3. To reduce the risk to nontarget plants, the labeling must be revised at the next label printing and prior to February 28, 2001 to add following precautionary statements:

Avoid all direct or indirect contact with nontarget plants.

Do not apply near desirable vegetation and allow adequate distance between target area and desirable plants to minimize exposure.

Do not apply under conditions which favor runoff or wind transport of soil containing diclosulam to nontarget areas

To prevent off-site movement due to runoff or wind erosion.

- Avoid treating powdery dry or light sandy soils when conditions are favorable for wind erosion. Under these conditions, the soil surface should first be settled by rainfall or irrigation.
- Do not apply to impervious substrates, such as paved or highly compacted surfaces or frozen or snow-covered ground.
- Do not apply to soils when saturated with water.
- Do not use water from the first flood or furrow irrigation from treated fields to irrigate nontarget crops unless there has been at least 1/2 inch of rainfall during the period between application and first irrigation.

Do not apply when weather conditions favor drift to nontarget sites. To minimize spray drift to nontarget areas:

- Use low pressure application equipment capable of producing a large droplet spray.

- Do not use nozzles that produce a fine droplet spray.
- Minimize drift by using sufficient spray volume to ensure adequate coverage with large droplet size sprays.
- Keep ground-driven spray boom as low as possible above the target surface.
- Spray only when there is no wind or when wind speed is low. Do not apply when wind is gusting or when wind speed is greater than 10 mph.

4. The Agency requests additional positive control data and untransformed motor activity data for the acute neurotoxicity study and the 1-year neurotoxicity study.

5. Submit two copies of the final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

If you have any questions about this letter, please contact Tobi Colvin-Snyder at 703-305-7801.

Jim Tompkins
Product Manager (25)
Herbicide Branch
Registration Division (7505C)

13A / Strongarm / Prop Sec 3 (Peanuts Only) / 03-01-00

(Base label):

(logo) Dow AgroSciences LLC [Stamp Omitted]

Strongarm*

For Broadleaf Weed Control in Peanuts

Active Ingredients:
diclosulam: N-(2,6-dichlorophenyl)-5-ethoxy-7-fluorol[1,2,4]triazolo-[1,5-c]pyrimidine-2-sulfonamide.....84%
Inert Ingredients.....16%
Total 100%

Contains 0.84 pounds of active ingredient per pound of product.

U.S. Patent No. 5,163,995

Keep Out of Reach of Children

CAUTION PRECAUCION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

Precautionary Statements

Hazards to Humans and Domestic Animals

Causes Moderate Eye Irritation. Harmful If Absorbed Through Skin

Avoid contact with eyes, skin, or clothing.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves

- Shoes plus socks

Follow manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

First Aid

If in eyes: Flush with plenty of water. Get medical attention if irritation persists.

If on skin: Wash with plenty of soap and water. Get medical attention if irritation persists.

Environmental Hazards

Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or when disposing of equipment washwaters.

This chemical and its transformation products demonstrate the properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.

This chemical can contaminate surface water through spray drift.

Under some conditions, this chemical, and/or its transformation products, may have a high potential for runoff into surface water (primarily via dissolution in runoff water), for several weeks post-application.

Vulnerable conditions include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. Refer to label booklet under "Agricultural Use Requirements" in the Directions for Use section for information about this standard.

Refer to label booklet for additional Directions for Use including Storage and Disposal.

Notice: Read the entire label. Use only according to label directions. **Before buying or using this product, read "Warranty Disclaimer" and "Limitation of Remedies" inside label booklet.**

In case of emergency endangering health or the environment involving this product, call 1-800-992-5994. If you wish to obtain additional product information, visit our web site at www.dowagro.com.

Agricultural Chemical: Do not ship or store with food, feeds, drugs or clothing.

EPA Reg. No. 62719-288 EPA Est. 00000-XX-00

*Trademark of Dow AgroSciences LLC

Dow AgroSciences LLC • Indianapolis, IN 46268 U.S.A.

Herbicide

Net Wt. __ lb

(Label Booklet cover):

(logo) Dow AgroSciences LLC

Strongarm*

For Broadleaf Weed Control in Peanuts

Active Ingredients:
diclosulam: N-(2,6-dichlorophenyl)-5-ethoxy-7-fluorol[1,2,4]triazolo-[1,5-c]pyrimidine-2-sulfonamide.....84%
Inert Ingredients.....16%
Total 100%

Contains 0.84 pounds of active ingredient per pound of product.

U.S. Patent No. 5,163,995

Keep Out of Reach of Children

CAUTION PRECAUCION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. Refer to label booklet under "Agricultural Use Requirements" in the Directions for Use section for information about this standard.

Refer to label booklet for additional precautionary information including Personal Protective Equipment (PPE), User Safety Recommendations

and Directions for Use including Storage and Disposal.

Notice: Read the entire label. Use only according to label directions. **Before buying or using this product, read "Warranty Disclaimer" and "Limitation of Remedies" inside label booklet.**

In case of emergency endangering health or the environment involving this product, call 1-800-992-5994. If you wish to obtain additional product information, visit our web site at www.dowagro.com.

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*Trademark of Dow AgroSciences LLC

Dow AgroSciences LLC • Indianapolis, IN 46268 U.S.A.

Herbicide

Net Wt __ lb

(Page 1 through end):

Precautionary Statements

Hazards to Humans and Domestic Animals

CAUTION

Causes Moderate Eye Irritation • Harmful If Absorbed Through Skin

Avoid contact with eyes, skin, or clothing.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Follow manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions for use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

First Aid

If in eyes: Flush with plenty of water. Get medical attention if irritation persists.
If on skin: Wash with plenty of soap and water. Get medical attention if irritation persists.

Environmental Hazards:

Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean

high water mark. Do not contaminate water by cleaning of equipment or when disposing of equipment washwaters.

This chemical and its transformation products demonstrate the properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.

This chemical can contaminate surface water through spray drift.

Under some conditions, this chemical, and/or its transformation products, may have a high potential for runoff into surface water (primarily via dissolution in runoff water), for several weeks post-application. Vulnerable conditions include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water.

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Read all Directions for Use carefully before applying.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your state or tribe, consult the agency responsible for pesticide regulation.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

Exception: If the product is soil-injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls
- Waterproof gloves
- Shoes plus socks

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store in original container only. In case of leak or spill, contain material with absorbent materials and dispose as waste.

Disposal: Wastes resulting from the use of this product may be disposed of on site according to label use directions or at an approved waste disposal facility.

Container Disposal: When all packets are used, dispose of empty package in a sanitary landfill or by incineration or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

General Information

Strongarm* herbicide is a soil-applied product for control of broadleaf weeds in peanuts. Strongarm may also be used postemergence in peanuts.

Soil application: A single preplant incorporated, preplant surface, or preemergence application may be made in peanuts.

Postemergence application: A single postemergence application may be made in peanuts.

General Use Precautions and Restrictions

Maximum Application Rates

- In peanuts, do not apply more than 0.45 oz of Strongarm per acre per year in any combination of preplant incorporated, preplant surface, preemergence or postemergence applications.
- **Note:** Only a single soil application per growing season may be made in peanuts.

Preharvest Interval

Do not harvest peanuts for 30 days following application.

Read and carefully follow all applicable directions, precautions and restrictions on labeling for other products used in combination with Strongarm.

Aerial application of this product is prohibited.

Do not allow livestock to graze treated areas or harvest forage or hay from treated areas.

Iron Chlorosis: There are isolated areas of the country where soil-induced iron chlorosis routinely occurs. Severity of iron chlorosis symptoms may increase when Strongarm is soil-applied in areas with a history of soil-induced iron chlorosis or other nutrient induced crop injury.

Proper Handling Instructions

This product may not be mixed or loaded within 50 feet of any wells (including abandoned wells and drainage wells), sink holes, perennial or intermittent streams and rivers, and natural or impounded lakes and reservoirs. This setback does not apply to properly capped or plugged abandoned wells and does not apply to impervious pad or properly diked mixing/loading areas.

Operations that involve mixing, loading, rinsing, or washing of this product into or from pesticide handling or application equipment or containers within 50 feet of any well are prohibited unless conducted on an impervious pad constructed to withstand the weight of the heaviest load that may be positioned on or moved across the pad. Such a pad shall be designed and maintained to contain any product spills or equipment leaks, container or equipment rinse or washwater, and rainwater that may fall on the pad. Surface water shall not be allowed to either flow over or from the pad, which means the pad must be self contained. The pad shall be sloped to facilitate material removal. An unroofed pad shall be of sufficient capacity to

contain at a minimum 110% of the capacity of the largest pesticide container or application equipment on the pad. A pad that is covered by a roof of sufficient size to completely exclude precipitation from contact with the pad shall have a minimum containment capacity of 100% of the capacity of the largest pesticide container or application equipment on the pad. Containment capacities as described above shall be maintained at all times. The above specific minimum containment capacities do not apply to vehicles when delivering pesticide shipments to the mixing/loading site. States may have in effect additional requirements regarding wellhead setbacks and operational containment.

Chemigation: Do not apply this product through any type of irrigation system.

Do not use flood irrigation to apply or incorporate this product.

This product must be used in a manner that will prevent back siphoning in wells, spills or improper disposal of excess pesticide, spray mixtures or rinsates.

Crop Rotation Interval for Common Crops

Crop	Rotation Interval (1) (Months)
soybeans, peanuts	no restriction
wheat, barley	4
oats, rye	6
cotton	10
corn (2), rice, tobacco, sorghum	18
sugar beets, sunflowers and other crop not listed	30 (3)

1. Minimum number of months that must pass before planting other crops after application of Strongarm at up to 0.45 oz/acre in peanuts.
2. The crop rotation interval for corn hybrids identified as "IR" is 10 months.
3. Rotation to sugar beets, sunflowers, and all other crops not listed requires a 30-month rotation interval and a successful field bioassay.

Field Bioassay Instructions

Using typical tillage, seeding practices, and timings for the particular crop, plant several strips of the desired crop variety across the field previously treated with Strongarm. Plant the steps perpendicular to the direction Strongarm was applied. The strips should also be located so that different field conditions are encountered, including differences in soil texture, pH, and drainage. If the crop does not show visible symptoms of injury, stand reduction, or yield reduction, the field can be seeded with the test crop in the growing season following the bioassay. If visible injury, stand reduction, or yield reduction occurs, the test crop should not be seeded, and the bioassay must be repeated the next growing season.

Mixing and Application

Spray Volume and Application

Apply Strongarm in sufficient spray volume to provide uniform coverage. A spray volume of 10 or more gallons per acre is recommended for soil applications. Sufficient agitation should be maintained during mixing and spraying to ensure a uniform spray mixture. Apply with ground equipment using standard low pressure (20 to 40 psi) herbicide sprayers equipped with nozzles that provide uniform spray coverage. Screens in lines should be finer than 50 mesh (100 mesh is finer than 50 mesh).

Strongarm Applied Alone

Strongarm water dispersible granules are provided in water soluble packets that require thorough mixing. **Note:** The water soluble packets are not soluble in liquid fertilizer. If applied in liquid fertilizer, Strongarm **must be** pre-mixed (slurried) with water and then added to the liquid fertilizer solution. Premixing may also be used to aid in mixing with water. See pre-mixing instructions below.

Handling Precautions for Water Soluble Packets: Do not remove water soluble packet from overpack except for immediate use. Do not open water soluble packets (product in transparent film). Do not allow water soluble packet to come into contact with water prior to use. Do not handle water soluble packet with wet hands or wet gloves. Carefully reseal overpack containing unused water soluble packets and protect package from moisture.

Determining the Number of Water Soluble Packets Required:

Application Rate (oz/acre)	Acres per Individual Bubble Packet
0.45+	1.0

Formula: Acres to be treated + Acres/Packet = Number of Packets

Mixing Order:

1. Fill the tank with 1/2 of the total amount of water or liquid fertilizer for the load. **Note:** If liquid fertilizer is being used as the spray carrier, water-soluble packets must be pre-mixed as described below before adding to the spray tank. Start the agitation system.
2. Add water soluble packets by opening the overpack and adding the packet (product in transparent film) directly into the spray tank while agitating. Before spraying, make sure packets have completely

disintegrated and product is thoroughly mixed with water. Depending on the water temperature and the degree of agitation, the packet and its contents should be completely dispersed within 5 minutes from the time they were added to the water.

3. Postemergence or burndown application: Add any surfactant or other adjuvant material last.

4. Continue agitation and finish filling tank.

Note: To ensure a uniform spray mixture continuous agitation is required during application. If product is allowed to settle, thoroughly agitate to resuspend the mixture before spraying. To ensure product effectiveness, apply within 24 hours of mixing. Weed control with Strongarm that has been mixed and allowed to stand for more than 48 hours may be reduced.

Strongarm Applied in Tank-mix Combination

If a broader spectrum of weed control is required, Strongarm may be tank-mixed with labeled rates of other herbicides provided: (1) the tank mix product is labeled for the timing and method of application for the use site to be treated; and (2) tank mixing is not prohibited by the label of the tank mix product.

Tank Mixing Precautions:

- Read carefully and follow all applicable use directions, precautions, and limitations on the respective product labels.
- Do not exceed recommended application rates for respective products or maximum allowable application rates for any active ingredient in the tank mix.
- For products packaged in water soluble packaging, do not tank mix with products containing boron or mix in equipment previously used to apply a product mixture containing boron unless the tank and spray equipment

has been adequately cleaned. (See Equipment Clean-Out Procedures.)

- Always perform a (jar) test to ensure, the compatibility of products to be used in tank mixture.

Tank Mix Compatibility Testing: A jar test is recommended prior to tank mixing to ensure compatibility of Strongarm and other pesticides. Use a clear glass quart jar with lid and mix the tank mix ingredients in their relative proportions. Invert the jar containing the mixture several times and observe the mixture for approximately 1/2 hour. The mixture balls-up, forms flakes, sludges, jels, oily films or layers, or other precipitates, it is not compatible and the tank mix combination should not be used.

Vigorous, continuous agitation during mixing, filling and throughout application is required for all tank-mixes. Sparger type agitators generally provide the most effective agitation in spray tanks. To prevent foaming in the spray tank, avoid stirring or splashing into the spray mixture.

Mixing Order for Tank-mixes:

1. Fill the spray tank to 1/2 of the total spray volume required with water or liquid fertilizer. **Note:** If liquid fertilizer is being used as the spray carrier, water-soluble packets must be pre-mixed as described below before adding to the spray tank. Start the agitation system.

2. Add water soluble packets by opening the overpack and adding water soluble packet (product in transparent film) directly into the spray tank while agitating and allow time to disperse. Allow time for complete mixing (approximately 5 minutes). Before adding other products, make sure packets have completely disintegrated and product is thoroughly mixed.

3. Add different formulation types in the following order: (1) Other formulation packaged in water soluble film; (2) Any compatibility agent, if required; (3) other dry flowables; (4) wettable powders; (5) aqueous suspensions, flowables and liquids. Maintain agitation and fill spray tank to 3/4 of total spray volume and add: (5) emulsifiable concentrates and (6) solutions (i.e., fertilizers). Allow time for complete mixing after each addition.
4. Postemergence or burndown application: Add any surfactant or other adjuvant material last.
5. Finish filling the spray tank. Maintain continuous agitation during mixing and throughout application.

If application or agitation must be stopped before the spray tank is empty, the materials may settle to the bottom. Settled materials must be re-suspended before spraying is resumed. A sparger agitator is particularly useful for this purpose. Settled material may be more difficult to re-suspend than when originally mixed.

Pre-mixing (Slurry) of Water Soluble Packets

The film used in water soluble packaging for Strongarm is not soluble in liquid fertilizer solutions. In order to add Strongarm to liquid fertilizer carrier, the product **must be** premixed with water. Pre-mixing is also an alternative mixing method for application in water. Use a minimum 2 fl oz. of water for each individual 0.45 oz water soluble packet of Strongarm. The packets can be stirred immediately on addition to water or allowed to dissolve. Stir (or shake if pre-mixed in a closed container) until the packets are completely dissolved and granules are dispersed and then add to the spray tank or inductor (recommended through a 20-35 mesh screen). Rinse container used for pre-mixing and add rinsate to spray tank.

Pre-mixing (other products): If pre-mixing is required for other dry or flowable products applied in tank-mix combination with Strongarm, follow recommendations for pre-mixing of such products provided in their respective product labels.

Equipment Clean-out Procedures:

1. Drain any remaining spray mixture from the application system.
2. Hose down the interior surfaces of the tank while filling the tank 1/2 full with water.
3. Add household ammonia, at a rate of 1 gallon per 100 gallons of water. Recirculate for 5 minutes and spray out part of this mixture for 5 minutes through the boom. Drain tank.
4. Remove all spray nozzles and screens and clean separately.

Note: If this spray equipment will be used on a crop that is sensitive to Strongarm, steps 1-3 should be repeated. Exterior surfaces of spray equipment should also be washed thoroughly.

All rinsate should be disposed of on site or at an approved waste disposal facility.

Application with Dry Bulk Fertilizer (Soil Application Only)

Dry bulk fertilizer may be impregnated or coated with Strongarm. Soil applications of Strongarm with dry bulk fertilizer can provide weed control equal to the same rates of Strongarm applied in liquid carriers. Follow label recommendations, including application rates, precautions and limitations for soil application.

Apply the recommended rate of Strongarm in 200 to 700 lb/acre of dry bulk fertilizer using calibrated equipment. To avoid caking, apply the mixture as soon as possible after blending. Uniform application of the herbicide/

fertilizer mixture essential for satisfactory weed control and to prevent possible crop injury.

In areas where conventional tillage is practiced, shallow soil incorporation of the mixture may improve weed control.

Some fertilizer blends tend to absorb moisture, especially under high humidity conditions. Under humid conditions, the addition of a drying agent such as Celatom or Microcel (diatomaceous earth) may be necessary to prevent caking. Use of a drying agent is recommended if the fertilizer mixture will not applied immediately.

Most absorbent dry fertilizers can be used for impregnation with Strongarm. Pure ammonium nitrate and/or limestone will not absorb the herbicide and are not suitable for impregnation with Strongarm. Absorbent fertilizer blends containing ammonium nitrate and/or limestone as part of a mixture may be suitable for impregnation.

Compliance with all Federal and State regulations relating to blending pesticide mixtures with dry bulk fertilizer registration, labeling and application are the responsibility of the individual and/or company offering the fertilizer and chemical mixture for sale.

Impregnation: Strongarm must be premixed with water to form a slurry prior to impregnation of dry bulk fertilizer. For best results, use a minimum of 6 fl oz of water for each individual 0.45 oz water soluble packet of product.

Pre-mixing can be accomplished by shaking the water soluble packets and water together in a closed container with a small amount of a silicon-based defoaming agent. Inspect the mixture to assure the Strongarm is completely dispersed in water and the water soluble packaging has completely dissolved. Add sufficient water to adjust the total volume of the mixture to deliver a spray volume of

0.5 to 1.0 gallons per ton of fertilizer. Use constant agitation to keep the spray mixture suspended.

Spray nozzle selection and placement are critical for uniform spray coverage. The recommended spray time is no less than 3-5 minutes per batch. Nozzle placement should minimize spray overlap in the blender and also avoid spraying the mixer walls. The use of a suitable in-line (no finer than 100-mesh) screen is also recommended to avoid spray blockages. Any closed drum, belt, ribbon or other commonly used dry bulk fertilizer blender may be used.

Calculate amounts of Strongarm by the following formula:

$\frac{2{,}000}{\text{Pounds of fertilizer per acre}}$	X	ounces/acre of Strongarm	=	ounces of product Stronarm per ton of fertilizer

Example:

$\frac{2{,}000}{\text{250 Lbs of fertilizer per acre}}$	X	0.45 ounces/acre of Strongarm	=	3.6 ounces of product per ton of fertilizer

Note: It is imperative to thoroughly flush the fertilizer dry blending equipment prior to preparing blends with other herbicides. Flushing may be accomplished by running 1-2 loads of dry fertilizer, which must be used only in peanuts or soybeans. Inspect the equipment carefully for any spray buildup or deposits from earlier batches and wash or remove as appropriate. Where possible, rinse the blenders with water, followed by bleach or ammonia solution. The rinsate can be mixed with the fertilizer used for flushing, but at no more than 1 gallon of rinsate per ton of fertilizer.

Approved Uses

PEANUTS (Soil Application)

Strongarm may be used in various tillage programs including, but not limited to, strip till, no tilt and conventional tillage operations. Application of Strongarm on soils with greater than 5% organic matter may result in reduced weed control and require subsequent postemergence applications of other herbicides appropriate for specific weeds. Do not use on peat or muck soils. Season-long control of severe weed infestations may require a postemergence application of complimentary herbicides following application of Strongarm.

***Note**: Environmental and soil factors can influence the performance and selectivity of any herbicide treatment. Rainfall of 0.5 inches or greater is required for optimum weed control by most soil herbicides, including Strongarm. Strongarm and other herbicides when incorporated will perform most optimally when evenly distributed in the surface soil. When emergence of the planted crop is delayed due to unusually cool and/or wet conditions, factors such as pH, disease, and nutrient deficiencies can contribute to reduced crop tolerance to a soil-applied herbicide.*

Cultivation: If required, cultivation should be shallow to avoid excessive movement of treated soil and to expose weed seed buried deep within the soil.

Area of Use (Peanuts): Use of Strongarm is recommended in all areas where peanuts are grown.

Application Rates	
Crop	Strongarm (oz/acre)
Peanuts	0.45
Weeds Controlled	
bristly starbur common cocklebur common lambsquarters common ragweed common sunflower eclipta devil's-claw Florida beggarweed giant ragweed morningglory species nutsedge species (1, 2) Palmer amaranth	Pennsylvania smartweed prickly sida redroot pigweedsmooth pigweed spurred anoda spurge species shining tickweed tropic croton Virginia Copper Leaf velvetleaf wild poinsetta

Note: Numbers in parentheses "(-)" refer to footnotes below.

1. Heavy infestations may require postemergence application of complimentary herbicides following a soil application of Strongarm for season-long control.
2. The level of nutsedge control provided by Strongarm on nutsedge can vary depending on weed density and soil or environmental conditions.

For best results:

- Fields should be clean-tilled and weed-free.
- Apply **Strongarm** as close as possible to planting.
- If irrigation is available, immediately apply 0.25 to 0.5 inch of water.
- Cultivation, a tank mixture, or applications of postemergence herbicides may also be needed to achieve desired level of control.

Application Directions

Preplant Incorporated Application

Apply Strongarm alone or in tank-mix combination with other herbicides registered for preplant incorporated application. Apply to a seedbed that is relatively free of clods. Incorporate the herbicide(s) into the top 1 to 3 inches of the final seedbed using equipment that provides thorough soil mixing. Do not apply Strongarm more than 4 weeks before planting. For optimum results, apply Strongarm at or just prior to planting. When Strongarm is applied in tank-mix combination with other herbicide(s), follow the incorporation directions for the tank-mix partner(s). Follow applicable use instructions, including application rates, precautions and restrictions of each product used in the tank-mixture.

Preplant Surface Application

Apply Strongarm alone or in tank-mix combination with other herbicides registered for preplant soil surface applications. Apply to a seedbed that is relatively free of clods. Do not apply Strongarm more than 4 weeks before planting. For optimum results, apply Strongarm at or just prior to planting. Soil surface applications are not effective until rainfall or irrigation of at least 0.25 - 0.5 inches has moved Strongarm into soil where weed germination occurs. If rainfall is not anticipated, shallow (i.e., 2 inches) incorporation prior to planting is recommended to place Strongarm in contact with germinating weeds. If applied in tank-mix combination, follow use instructions, including application rates, precautions and restrictions of each product used in the tank-mixture. For minimum-tillage or no tillage or reduced tillage systems, when weeds are present at the time of application, apply in a tank mix combination a contact herbicide such as Starfire or Roundup herbicide.

Note: Reduced weed control in the planted row may occur from exposure of untreated soil during the planting

operation if surface applications are not incorporated prior to planting.

Burndown Application

When used as a no-till burndown application, Strongarm provides foliar control of specific broadleaf weeds (mostly starbur, common cocklebur, common and giant ragweed, common sunflower, Florida beggarweed, morning glory species, tropic croton, and velvetleaf) and residual control of broadleaf weeds listed above for soil applied applications. For optimum results, apply Strongarm within 2 weeks of planning. If applied as a burndown application in tank-mix combination with another herbicide(s), use only adjuvants that are recommended for the tank-mix partner(s). When tank-mixing with other herbicides, a jar test for compatibility is always recommended (see "Compatibility Testing" in the "Mixing and Application" section).

Mixing Order: When tank mixing with glyphosate and ammonium sulfate, add ammonium sulfate to the tank mixture before adding glyphosate.

Preemergence Application

Apply after planting but prior to crop or weed emergence. Preemergence applications are not effective until rainfall or irrigation of at least 0.25 - 0.5 inches has moved Strongarm into the soil where weed germination occurs. Strongarm may be applied alone or in tank-mix combination with herbicides registered for preemergence application. When applied in tank-mix combination, follow applicable use instructions, including application rates, precautions and restrictions of each product used in the tank-mixture. For optimum results, Strongarm should be applied at or near planting, prior to germination of weeds and emergence of the crop.

Postemergence Application (Peanuts Only)

Apply Strongarm as a broadcast spray when weeds are in the 1 to 4 leaf stage and actively growing. Applications made to larger weeds or to weeds under stress may result in unsatisfactory control. Optimum weed control will be obtained by applying Strongarm under favorable growing conditions (i.e., moisture and adequate soil temperature). Applications may occur from peanut cracking through pegging.

Strongarm may be applied alone or in tank mix combination with other postemergence herbicides registered for use in peanuts. Applications of Strongarm must include either a crop oil concentrate, or a nonionic surfactant.

Weeds Controlled	Strongarm (oz/acre)
common cocklebur common ragweed Florida beggarweed hemp sesbania morningglory species nutsedge species pricky sida smartweed spurge species velvetleaf	0.15 - 0.45

Adjuvant Systems for Postemergence Application

Use in combination with one of the following adjuvant systems approved for application to growing crops:

- Nonionic surfactant (0.125 - 0.25% v/v)

- Nonionic surfactant (0.125 - 0.25% v/v) plus urea ammonium nitrate solution (2.5% v/v); dry ammonium sulfate may be used at a rate of 2 lbs per acre as a substitute for urea ammonium nitrate.
- Crop oil concentrate or methylated seed oil (1.2% v/v)
- Crop oil concentrate or methylated seed oil (1.2% v/v) plus urea ammonium nitrate solution (2.5% v/v)

Note: Use of crop oil concentrate or methylated seed oil plus urea ammonium nitrate is preferred when weeds are under drought stress, but may increase crop injury.

Tank Mix Applications

When applied in tank mix combination with other herbicides follow applicable use instructions, including application rates, precautions and restrictions for each product used in the tank mixture, including use of adjuvants.

Minimum Tillage, No Tillage, Strip Tillage, or other reduced tillage systems

In these tillage systems, where peanuts are planted directly into a cover crop, stale seedbed, or previous crop residues, a contact herbicide such as Starfire or Roundup may be tank mixed with Strongarm to control existing weeds. Apply before, during (behind the planter), or after planting, but before the crop emerges.

Strongarm Followed by Postemergence Treatments

Weeds and grasses not controlled by Strongarm may be controlled with postemergence herbicide products. Follow the postemergence manufacturer's labels for application rates, weeds controlled, applicable use directions, precautions and limitations before use.

Warranty Disclaimer

Dow AgroSciences warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in strict accordance with the directions, subject to the inherent risks set forth below. Dow AgroSciences MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

Inherent Risks of Use

It is impossible to eliminate all risks associated with use of this product. Crop injury, lack of performance, or other unintended consequences may result because of such factors as use of the product contrary to the label instructions (including adverse conditions noted on the label, such as unfavorable temperatures, soil conditions, etc.), abnormal conditions (such as excessive rainfall, drought, tornadoes, hurricanes), presence of other materials, the manner of application, or other factors, all of which are beyond the control of Dow AgroSciences or the seller. All such risks shall be assumed by the buyer.

Limitation of Remedies

The exclusive remedy for losses or damages resulting from the use of this product (including claims based on contract, negligence, strict liability, or other legal theories), shall be limited to, at Dow AgroSciences' election, one of the following:

1. Refund of purchase price paid by buyer or user for product bought, or

2. Replacement of amount of product used.

Dow AgroSciences shall not be liable for losses or damages resulting from handling or use of this product unless Dow AgroSciences is promptly notified of such loss or damage

in writing. In no case shall Dow AgroSciences be liable for consequential or incidental damages or losses.

The terms of the Warranty Disclaimer above and this Limitation of Remedies cannot be varied by any written or verbal statements or agreements. No employee or sales agent of Dow AgroSciences or the seller is authorized to vary or exceed the terms of the Warranty Disclaimer or this Limitation of Remedies in any manner.

*Trademark of Dow AgroSciences LLC

EXHIBIT B

Specimen Label

[logo omitted] Dow AgroSciences LLC

Strongarm*

*Trademark of Dow AgroSciences LLC

For Broadleaf Weed Control in Peanuts

Active Ingredients:
diclosulam: N-(2,6-dichlorophenyl)-5-ethoxy-7-fluorol[1,2,4]triazolo-[1,5-c]pyrimidine-2-sulfonamide.....84%
Inert Ingredients.....16%
Total 100%

Contains 0.84 pounds of active ingredient per pound of product.

U.S. Patent No. 5,163,995

EPA Reg. No. 62719-288

Keep Out of Reach of Children

CAUTION PRECAUCION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

Precautionary Statements

Hazards to Humans and Domestic Animals

Causes Moderate Eye Irritation; Harmful If Absorbed Through Skin

Avoid contact with eyes, skin, or clothing.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear.

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

First Aid

If in eyes: Flush with plenty of water. Get medical attention if irritation persists.

If on skin: Wash with plenty of soap and water. Get medical attention if irritation persists.

Environmental Hazards

Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or when disposing of equipment washwaters.

This chemical and its transformation products demonstrate the properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.

This chemical can contaminate surface water through spray drift.

Under some conditions, this chemical, and/or its transformation products, may have a high potential for runoff into surface water (primarily via dissolution in runoff water), for several weeks post-application. Vulnerable conditions include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water.

Notice: Read the entire label. Use only according to label directions. **Before buying or using this product, read "Warranty Disclaimer" and "Limitation of Remedies" elsewhere on this label.**

In case of emergency endangering health or the environment involving this product, call 1-800-992-5994. If you wish to obtain additional product information, visit our web site at www.dowagro.com.

Agricultural Chemical: Do not ship or store with food, feeds, drugs or clothing.

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Read all Directions for Use carefully before applying.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your state or tribe, consult the agency responsible for pesticide regulation.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours. **Exception:** If the product is soil-injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls
- Waterproof gloves
- Shoes plus socks

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store in original container only. In case of leak or spill, contain material with absorbent materials and dispose as waste.

Disposal: Wastes resulting from the use of this product may be disposed of on site according to label use directions or at an approved waste disposal facility.

Container Disposal: When all packets are used, dispose of empty package in a sanitary landfill or by incineration or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

General Information

Strongarm* herbicide is a soil-applied product for control of broadleaf weeds in peanuts. Strongarm may also be used postemergenoe in peanuts.

Soil application: A single preplant incorporated, preplant surface, or preemergence application may be made in peanuts.

General Use Precautions and Restrictions

Maximum Application Rates

- In peanuts, do not apply more than 0.45 oz of Strongarm per acre per year in any combination of preplant incorporated, preplant surface, preemergence or postemergence applications.
- **Note:** Only a single soil application per growing season may be made in peanuts.

Preharvest Interval

- Do not harvest peanuts for 30 days following application.

Read and carefully follow all applicable directions, precautions and restrictions on labeling for other products used in combination with Strongarm.

Aerial application of this product is prohibited.

Do not allow livestock to graze treated areas or harvest forage or hay from treated areas.

Iron Chlorosis: There are isolated areas of the country where soil-induced iron chlorosis routinely occurs. Severity of iron chlorosis symptoms may increase when Strongarm is soil-applied in areas with a history of soil-induced iron chlorosis or other nutrient induced crop injury.

Proper Handling Instructions

This product may not be mixed or loaded within 50 feet of any wells (including abandoned wells and drainage wells), sink holes, perennial or intermittent streams and rivers, and natural or impounded lakes and reservoirs. This setback does not apply to properly capped or plugged abandoned wells and does not apply to impervious pad or properly diked mixing/loading areas.

Operations that involve mixing, loading, rinsing, or washing of this product into or from pesticide handling or application equipment or containers within 50 feet of any well are prohibited unless conducted on an impervious pad constructed to withstand the weight of the heaviest load that may be positioned on or moved across the pad. Such a pad shall be designed and maintained to contain any product spills or equipment leaks, container or equipment rinse or washwater, and rainwater that may fall on the pad. Surface water shall not be allowed to either flow over or from the pad, which means the pad must be self contained. The pad shall be sloped to facilitate material removal. An unroofed pad shall be of sufficient capacity to contain at a minimum 110% of the capacity of the largest pesticide container or application equipment on the pad.

A pad that is covered by a roof of sufficient size to completely exclude precipitation from contact with the pad shall have a minimum containment capacity of 100% of the capacity of the largest pesticide container or application equipment on the pad. Containment capacities as described above shall be maintained at all times. The above specific minimum containment capacities do not apply to vehicles when delivering pesticide shipments to the mixing/loading site. States may have in effect additional requirements regarding wellhead setbacks and operational containment.

Chemigation: Do not apply this product through any type of irrigation system.

Do not use flood irrigation to apply or incorporate this product.

This product must be used in a manner that will prevent back siphoning in wells, spills or improper disposal of excess pesticide, spray mixtures or rinsates.

Precautions for Avoiding Injury to Nontarget Plants

Avoid all direct or indirect contact with nontarget plants.

Do not apply near desirable vegetation and allow adequate distance between target area and desirable plants to minimize expsoure.

Do not apply under considitions that favor runoff or wind transport of soil containing diclosulam to nontarget areas.

To prevent off-site movement due to runofff or wind erosion:

- Avoid treating powdery dry or light sand soils when conditions are favorable for wind erosion. Under these conditions, the soil surface should first be settled by rainfall or irrigation.
- Do not apply to impervious substrates, such as paved or highly compacted surfaces or frozen or snow-covered ground.

- Do not apply to soils when saturated with water.
- Do not use water from the first flood or furrow irrigation from treated fields to irrigate nontarget crops unless there has been at least 1/2 inch of rainfall during the period between application and first irrigation.

Do not apply when weather conditions favor drift to nontarget sites. To minimize spray drift to nontarget areas:

- Use low-pressure application equipment capable of producing a large droplet spray.
- Do not use nozzles that produce a fine droplet spray.
- Minimize drift by using sufficient spray volume to ensure adequate coverage with large droplet size sprays.
- Keep ground-driven spray boom as low as possible above the target surface.
- Spray only when there is no wind or when wind speed is low. Do not apply when wind is gusting or when wind speed is greater than 10 mph.

Crop Rotation Interval for Common Crops

Crop	Rotation Interval (1) (Months)
soybeans, peanuts	no restriction
wheat, barley	4
oats, rye	6
cotton	10
corn (2), rice, tobacco, sorghum	18
sugar beets, sunflowers and other crop not listed	30 (3)

1. Minimum number of months that must pass before planting other crops after application of Strongarm at up to 0.45 oz/acre in peanuts.
2. The crop rotation interval for corn hybrids identified as "IR" is 10 months.
3. Rotation to sugar beets, sunflowers, and all other crops not listed requires a 30-month rotation interval and a successful field bioassay.

Field Bioassay Instructions

Using typical tillage, seeding practices, and timings for the particular crop, plant several strips of the desired crop variety across the field previously treated with Strongarm. Plant the strips perpendicular to the direction Strongarm was applied. The strips should also be located so that different field conditions are encountered, including differences in soil texture, pH, and drainage. If the crop does not show visible symptoms of injury, stand reduction, or yield reduction, the field can be seeded with the test crop in the growing season following the bioassay. If visible injury stand reduction, or yield reduction occurs, the test crop should not be seeded, and the bioassay must be repeated the next growing season.

Mixing and Application

Spray Volume and Application

Apply Strongarm in sufficient spray volume to provide uniform coverage. A spray volume of 10 or more gallons per acre is recommended for soil applications. Sufficient agitation should be maintained during mixing and spraying to ensure a uniform spray mixture. Apply with ground equipment using standard low pressure (20 to 40 psi) herbicide sprayers equipped with nozzles that provide uniform spray coverage. Screens in lines should be finer than 50 mesh (100 mesh is finer than 50 mesh).

Strongarm Applied Alone

Strongarm water dispersible granules are provided in water soluble packets that require thorough mixing. **Note:** The water soluble packets are not soluble in liquid fertilizer. If applied in liquid fertilizer, Strongarm **must be** pro-mixed (slurried) with water and then added to the liquid fertilizer solution. Premixing may also be used to aid in mixing with water. See pre-mixing instructions below.

Handling Precautions for Water Soluble Packets: Do not remove water soluble packet from overpack except for immediate use. Do not open water soluble packets (product in transparent film). Do not allow water soluble packet to come into contact with water prior to use. Do not handle water soluble packet with wet hands or wet gloves. Carefully reseal overpack containing unused water soluble packets and protect package from moisture.

Determining the Number of Water Soluble Packets Required:

Application Rate (oz/acre)	Acres per Individual Bubble Packet
0.45	1.0

Formula: Acres to be treated + Acres/Packet = Number of Packets

Mixing Order:

1. Fill the tank with 1/2 of the total amount of water or liquid fertilizer for the toad. **Note:** If liquid fertilizer is being used as the spray carrier, water-soluble packets must be pre-mixed as described below before adding to the spray tank. Start the agitation system.
2. Add water soluble packets by opening the overpack and adding the packet (product in transparent film) directly into the spray tank while agitating. Before spraying, make sure packets have completely

disintegrated and product is thoroughly mixed with water. Depending on the water temperature and the degree of agitation, the packet and its contents should be completely dispersed within 5 minutes from the time they were added to the water.

3. Continue agitation and finish filling tank.

Note: To ensure a uniform spray mixture continuous agitation is required during application. If product is allowed to settle, thoroughly agitate to resuspend the mixture before spraying. To ensure product effectiveness, apply within 24 hours of mixing. Weed control with Strongarm that has been mixed and allowed to stand for more than 48 hours may be reduced.

Strongarm Applied in Tank-mix Combination

If a broader spectrum of weed control is required, Strongarm may be tank-mixed with labeled rates of other herbicides provided: (1) the tank mix product is labeled for the timing and method of application for the use site to be treated; and (2) tank mixing is not prohibited by the label of the tank mix product.

Tank Mixing Precautions:

- Read carefully and follow all applicable use directions, precautions, and limitations on the respective product labels.
- Do not exceed recommended application rates for respective products or maximum allowable application rates for any active ingredient in the tank mix.
- For products packaged in water soluble packaging, do not tank mix with products containing boron or mix in equipment previously used to apply a product mixture containing boron unless the tank and spray equipment has been adequately cleaned. (See Equipment Clean-Out Procedures.)
- Always perform a (jar) test to ensure, the compatibility of products to be used in tank mixture.

Tank Mix Compatibility Testing: A jar test is recommended prior to tank mixing to ensure compatibility of Strongarm and other pesticides. Use a clear glass quart jar with lid and mix the tank mix ingredients in their relative proportions. Invert the jar containing the mixture several times and observe the mixture for approximately 1/2 hour. If the mixture balls-up, forms flakes, sludges, jels, oily films or layers, or other precipitates, it is not compatible and the tank mix combination should not be used.

Vigorous, continuous agitation during mixing, filling and throughout application is required for all tank mixes. Sparger type agitators generally provide the most effective agitation in spray tanks. To prevent foaming in the spray tank, avoid stirring or splashing into the spray mixture.

Mixing Order for Tank-mixes:

1. Fill the spray tank to 1/2 of the total spray volume required with water or liquid fertilizer. **Note:** If liquid fertilizer is being used as the spray carrier, water-soluble packets must be pre-mixed as described below before adding to the spray tank. Start the agitation system.
2. Add water soluble packets by opening the overpack and adding water soluble packet (product in transparent film) directly into the spray tank while agitating and allow time to disperse. Allow time for complete mixing (approximately 5 minutes). Before adding other products, make sure packets have completely disintegrated and product is thoroughly mixed.
3. Add different formulation types in the following order: (1) Other formulation packaged in water soluble film; (2) Any compatibility agent, if required; (3) other dry flowables; (4) wettable powders; (5) aqueous suspensions, –flowables and liquids. Maintain agitation and fill spray tank to 3/4 of total

spray volume and add: (5) emulsifiable concentrates and (6) solutions (i.e., fertilizers). Allow time for complete mixing after each addition.

4. Finish filling the spray tank. Maintain continuous agitation during mixing and throughout application.

If application or agitation must be stopped before the spray tank is empty, the materials may settle to the bottom. Settled materials must be re-suspended before spraying is resumed. A sparger agitator is particularly useful for this purpose. Settled material may be more difficult to re-suspend than when originally mixed.

Pre-mixing (Slurry) of Water Soluble Packets

The film used in water soluble packaging for Strongarm is not soluble in liquid fertilizer solutions. In order to add Strongarm to liquid fertilizer carrier, the product must be premixed with water. Pre-mixing is also an alternative mixing method for application in water. Use a minimum 2 fl oz of water for each individual 0.45 oz water soluble packet of Strongarm. The packets can be stirred immediately on addition to water or allowed to dissolve. Stir (or shake if pre-mixed in a closed container) until the packets are completely dissolved and granules are dispersed and then add to the spray tank or inductor (recommended through a 20-35 mesh screen). Rinse container used for pre-mixing and add rinsate to spray tank.

Pre-mixing (other products): If pre-mixing is required for other dry or flowable products applied in tank-mix combination with Strongarm, follow recommendations for pre-mixing of such products provided in their respective product labels.

Equipment Clean-out Procedures:

1. Drain any remaining spray mixture from the application system.

2. Hose down the interior surfaces of the tank while filling the tank 1/2 full with water.

3. Add household ammonia, at a rate of 1 gallon per 100 gallons of water. Recirculate for 5 minutes and spray out part of this mixture for 5 minutes through the boom. Drain tank.

4. Remove all spray nozzles and screens and clean separately.

Note: If this spray equipment will be used on a crop that is sensitive to Strongarm, steps 1-3 should be repeated. Exterior surfaces of spray equipment should also be washed thoroughly.

All rinsate should be disposed of on site or at an approved waste disposal facility.

Approved Uses

PEANUTS (Soil Application)

Strongarm may be used in various tillage programs including, but not limited to, strip till, no tilt and conventional tillage operations. Application of Strongarm soils with greater than 5% organic matter may result in reduced weed control and require subsequent postemergence applications of other herbicides appropriate for specific weeds. Do not use on peat or muck soils. Season-long control of severe weed infestations may require a postemergence application of complimentary herbicides following application of Strongarm.

***Note**: Environmental and soil factors can influence the performance and selectivity of any herbicide treatment. Rainfall of 0.5 inches or greater is required for optimum weed control by most soil herbicides, including Strongarm. Strongarm and other herbicides when incorporated will perform most optimally when evenly distributed in the surface soil. When emergence of the planted crop is delayed*

due to unusually cool and/or wet conditions, factors such as pH, disease, and nutrient deficiencies can contribute to reduced crop tolerance to a soil-applied herbicide.

Cultivation: If required, cultivation should be shallow to avoid excessive movement of treated soil and to expose weed seed buried deep within the soil.

Area of Use (Peanuts): Use of Strongarm is recommended in all areas where peanuts are grown.

Application Rates	
Crop	Strongarm (oz/acre)
Peanuts	0.45
Weeds Controlled	
bristly starbur common cocklebur common lambsquarters common ragweed common sunflower eclipta devil's-claw Florida beggarweed giant ragweed morningglory species nutsedge species (1, 2) Palmer amaranth	Pennsylvania smartweed prickly sida redroot pigweedsmooth pigweed spurred anoda spurge species shining tickweed tropic croton Virginia Copper Leaf velvetleaf wild poinsetta

Note: Numbers in parentheses "(-)" refer to footnotes below.

1. Heavy infestations may require postemergence application of complimentary herbicides following a soil application of Strongarm for season-long control.

2. The level of nutsedge control provided by Strongarm on nutsedge can vary depending on weed density and soil or environmental conditions.

For best results:

Fields should be clean-tilled and weed-free.

- Apply **Strongarm** as close as possible to planting.
- If irrigation is available, immediately apply 0.25 to 0.5 inch of water.
- Cultivation, a tank mixture, or applications of postemergence herbicides may also be needed to achieve desired level of control.

Application Directions

Preplant Incorporated Application

Apply Strongarm alone or in tank-mix combination with other herbicides registered for preplant incorporated application. Apply to a seedbed that is relatively free of clods. Incorporate the herbicide(s) into the top 1 to 3 inches of the final seedbed using equipment that provides thorough soil mixing. Do not apply Strongarm more than 4 weeks before planting. For optimum results, apply Strongarm at or just prior to planting. When Strongarm is applied in tank-mix combination with other herbicide(s), follow the incorporation directions for the tank-mix partner(s). Follow applicable use instructions, including application rates, precautions and restrictions of each product used in the tank-mixture.

Preplant Surface Application

Apply Strongarm alone or in tank-mix combination with other herbicides registered for preplant soil surface applications. Apply to a seedbed that is relatively free of clods. Do not apply Strongarm more than 4 weeks before planting. For optimum results, apply Strongarm at or just prior to planting. Soil surface applications are not effective until rainfall or irrigation of at least 0.25 - 0.5 inches has moved Strongarm into soil where weed germination occurs. If rainfall is not anticipated, shallow (i.e., 2 inches) incorporation prior to planting is

recommended to place Strongarm in contact with germinating weeds. If applied in tank-mix combination, follow use instructions, including application rates, precautions and restrictions of each product used in the tank-mixture. For minimum-tillage or no tillage or reduced tillage systems, when weeds are present at the time of application, apply in a tank mix combination a contact herbicide such as Starfire or Roundup herbicide.

Note: Reduced weed control in the planted row may occur from exposure of untreated soil during the planting operation if surface applications are not incorporated prior to planting.

Preemergence Application

Apply after planting but prior to crop or weed emergence. Preemergence applications are not effective until rainfall or irrigation of at least 0.25 - 0.5 inches has moved Strongarm into the soil where weed germination occurs. Strongarm may be applied alone or in tank-mix combination with herbicides registered for preemergence application. When applied in tank-mix combination, follow applicable use instructions, including application rates, precautions and restrictions of each product used in the tank-mixture. For optimum results, Strongarm should be applied at or near planting, prior to germination of weeds and emergence of the crop.

Minimum Tillage, No Tillage, Strip Tillage, or other reduced tillage systems

In these tillage systems, where peanuts are planted directly into a cover crop, stale seedbed, or previous crop residues, a contact herbicide such as Starfire or Roundup may be tank mixed with Strongarm to control existing weeds. Apply before, during (behind the planter), or after planting, but before the crop emerges.

Strongarm Followed by Postemergence Treatments

Weeds and grasses not controlled by Strongarm may be controlled with postemergence herbicide products. Follow the postemergence manufacturer's labels for application rates, weeds controlled, applicable use directions, precautions and limitations before use.

Warranty Disclaimer

Dow AgroSciences warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in strict accordance with the directions, subject to the inherent risks set forth below. Dow AgroSciences MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

Inherent Risks of Use

It is impossible to eliminate all risks associated with use of this product. Crop injury, lack of performance, or other unintended consequences may result because of such factors as use of the product contrary to the label instructions (including adverse conditions noted on the label, such as unfavorable temperatures, soil conditions, etc.), abnormal conditions (such as excessive rainfall, drought, tornadoes, hurricanes), presence of other materials, the manner of application, or other factors, all of which are beyond the control of Dow AgroSciences or the seller. All such risks shall be assumed by the buyer.

Limitation of Remedies

The exclusive remedy for losses or damages resulting from the use of this product (including claims based on contract,

negligence, strict liability, or other legal theories), shall be limited to, at Dow AgroSciences' election, one of the following:

1. Refund of purchase price paid by buyer or user for product bought, or
2. Replacement of amount of product used.

Dow AgroSciences shall not be liable for losses or damages resulting from handling or use of this product unless Dow AgroSciences is promptly notified of such loss or damage in writing. In no case shall Dow AgroSciences be liable for consequential or incidental damages or losses.

The terms of the Warranty Disclaimer above and this Limitation of Remedies cannot be varied by any written or verbal statements or agreements. No employee or sales agent of Dow AgroSciences or the seller is authorized to vary or exceed the terms of the Warranty Disclaimer or this Limitation of Remedies in any manner.

*Trademark of Dow AgroSciences LLC

Dow AgroSciences LLC • Indianapolis, IN 46268 U.S.A.

Label Code: D02-044-003
Replaces LabeL D02-044-002

EPA-accepted 03-08-2000

Revisions:

1. Added Precautions for Avoiding Injury to Nontarget Plants.

Specimen Label Revised 12-06-00

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action
	)	No. 5-01CV0331-C
DENNIS BATES, [*et al.*],	)	
	)	
Defendants.	)	

AFFIDAVIT OF WILLIAM D. SCHAFER

William D. Schafer, being duly sworn, deposes and states:

1. My name is William D. Schafer. I am an adult, over the age of 21 years and I am competent to testify as to all matters stated herein.

2. I am employed as Quality Coordinator **(job title)** for Dow AgroSciences LLC (hereinafter "Dow AgroSciences"). I am fully familiar with the facts and circumstances discussed herein and allege the same based on personal knowledge and on the records of Dow AgroSciences.

3. Strongarm* is the registered trademark for a herbicide developed, manufactured, and marketed by Dow AgroSciences.

4. Diclosulam is the active herbicidal ingredient in Strongarm herbicide.

5. The Strongarm herbicide sold within the United States by Dow AgroSciences is produced at a

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* Trademark of Dow AgroSciences LLC

manufacturing facility for which I am responsible, located in Midland, Michigan.

6. Dow AgroSciences maintains strict adherence to quality control measures at this manufacturing facility to assure that both the technical grade diclosulam used in its Strongarm and the end-use formulation of Strongarm, are produced in compliance with Dow AgroSciences' production specifications and the EPA-approved confidential statements of formula for these products.

7. These quality control measures require that each and every lot of technical grade diclosulam produced by Dow AgroSciences be separately tested, under laboratory conditions, to assure compliance with Dow AgroSciences' production specifications and the EPA-approved confidential statement of formula for technical grade diclosulam.

8. Similarly, these quality control measures require that each and every lot of each end use formulation of Strongarm herbicide produced by Dow AgroSciences also be separately tested, under laboratory conditions, to assure compliance with Dow AgroSciences' production specifications and the EPA-approved confidential statement of formula for that end use formulation.

9. No Strongarm herbicide manufactured by Dow AgroSciences may be sold or distributed by Dow AgroSciences unless it has first been established to have passed the aforementioned quality control tests.

10. Dow AgroSciences maintains retainer samples from each produced lot of diclosulam and end-use Strongarm herbicide for three (3) years plus the current year. If a particular lot number is identified, Dow AgroSciences can produce the retainer samples and demonstrate compliance with all production specifications and the EPA-approved confidential statement of formula for that product. The lot numbers are identified on each

container of each Strongarm herbicide sold or distributed by Dow AgroSciences.

11. The aforementioned quality control measures are currently in place and have been in place since 2000 when, upon information and belief, the herbicide application at issue in this lawsuit took place.

And further the affiant sayeth not.

/s/ William D. Schafer
William D. Schafer

[Notary Omitted]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action
	)	No. 5-01CV0331-C
DENNIS BATES, [*et al.*],	)	
	)	
Defendants.	)	

[Filed Apr. 2, 2002]

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Respectfully submitted,

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/s/ Phil Watkins
By: PHIL WATKINS
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ATTORNEYS FOR DEFENDANTS

[Text Omitted, Exhibits Excerpted]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action
	)	No. 5-01CV0331-C
DENNIS BATES, [*et al.*],	)	
	)	
Defendants.	)	

AFFIDAVIT OF JOHN M. BROWN, Ph.D.

THE STATE OF TEXAS §
COUNTY OF BEXAR §

Before me, the undersigned notary public, on this day personally appeared JOHN M. BROWN, PH.D., who, after being on his oath duly sworn, deposed as follows:

1. My name is John M. Brown. I am over the age of 21 years and I am competent to make this affidavit. I have never been convicted of a felony and I have personal knowledge of the facts stated herein due to my education, training, experience and personal viewing. All of the facts stated in this affidavit are true and correct.

2. My address is 7900 O'Neal Road, Columbia, Missouri 65202. I have a Bachelor of Science in Agriculture Business from East Texas State University, a Masters of Science Degree in Floriculture from Texas A&M University and a Doctorate Degree in Horticulture from North Carolina State University. In my undergraduate and graduate education I took courses in

general horticulture, orchard management, plant physiology, plant nutrition, plant entomology and plant pathology. During the course of my graduate education, I conducted field investigations including the evaluation and analysis of herbicide damage upon plants under the direction of Dr. Ed McWilliams at Texas A&M University.

3. After receiving my doctorate degree in horticulture in 1987, I was employed with the University of Missouri and the Missouri Agricultural Extension Service. My duties included giving horticulture advise and assistance to farmers and growers. I taught courses on plant disorders to growers and performed on-site consultations with growers, chemical companies and the Missouri Agricultural Extension Service.

4. From January, 1989 to August, 1993, I was an assistant professor of horticulture in the Department of Plant Science at the University of Missouri-Columbia. My duties included working with the Agricultural Extension Service and working with the plant laboratory studying plant disorders. As a part of my study in the plant laboratory studying plant disorders, we evaluated and analyzed herbicide damage upon plants in a laboratory and farm setting. I also taught classes at the University of Missouri in Horticulture.

5. In September, 1993, I founded Agricultural Investigation and Research Corp. (AIR, Corp.). AIR, Corp. serves as a consultant in the investigation of plant disorders chiefly related to pesticide and herbicide damage. AIR, Corp. is located at 7900 O'Neal Road, Columbia, Missouri.

6. When asked to determine the causes of plant disorder in peanut crops, I have been taught in my undergraduate and graduate education to begin with the history of the peanut farms which includes oral information from the farm owner, manager and other persons who are familiar with the farm and the

accumulation of written information concerning the soils, irrigation water, horticulture practices, including fertilizer program, weed management program, pesticide program, fungicide program, general farm management and peanut production. After gathering this information, I conduct a visual inspection of the farm to observe any symptoms upon the peanut plants. The inspection of the peanut farm includes gathering peanut plants, soil and water for laboratory analysis, taking photographs and video of the farm, plants and farm operations. On the peanut plant itself, I will examine the leaves, stem, seed and roots. The investigation inspection methods which I have outlined above have been taught to me in the various horticulture courses that I have taken in my undergraduate and graduate education.

7. Based on my study of the Dow AgroSciences LLC herbicide Strongarm together with research that I have done with its label instructions together with my studies, I am familiar with®'s mode of action. The active ingredient in Strongarm is diclosulam. Diclosulam is a member of the Triazolopyrimidine sulfonanilide family of herbicides. The mode of action for diclosulam in plants is the inhibition of the enzyme acetolactate synthase (ALS). This enzyme catalyzes the first step in branch-chain (essential) amino acid biosynthesis. This pathway leads to the synthesis of valine, leucine and isoleucine and is unique in plants. Blocking this pathway deprives the plant of these essential amino acids, thus interferes with DNA synthesis and cell growth leading to plant destruction. ALS herbicides are absorbed by the roots, shoots and foliage and translocate throughout the plant in the xylem and phloem. ALS herbicides accumulate in the meristematic growing points of the plant such as the apical buds at the tips of roots, shoots, leaf axils and reproductive structures. Inhibition of plant growth will occur rapidly but visible symptoms of plant response may not show up for one to three weeks depending on the plant species, soil activity and environmental conditions.

8. Beginning in the spring of 2001, I was contacted by numerous farmers and peanut growers with complaints that their 2001 crops of wheat, corn and cotton were not growing in a normal fashion following the use of Strongarm in the growing year 2000 for peanuts. As I began to evaluate these complaints, the farmers and growers provided me with photographs, videotapes and verbal descriptions of the appearance of their 2000 peanut plants and crops. In addition, I visited Comanche Horizon Corporation's farm in Gaines and Andrews Counties and visited at least twenty farms in Oklahoma. The physical description of plant injury was similar in west Texas and in Oklahoma. The photographs and videotape taken of peanuts from various west Texas farms and Oklahoma farms were similar. The descriptions and physical appearance of injury to peanut plants included severe growth inhibition, crop yellowing (chlorosis), root injury, root necrosis (death), severe stunting of the plant throughout the growing season, failure of the peanuts to overlap in the rows and reduced yield and production.

9. Based on my research, typical soil and water pH in the peanut farming regions of west Texas is 7.0 and above. There is good scientific evidence which I believe to suggest that injury to the 2000 peanut crop resulted from high pH of the soil and irrigation water causing a greater availability of diclosulam in the plant-root environment.

10. As a research horticulturist one of the studies that we are taught to rely on is field research performed by agricultural extension services, county agents and university scientists, as well as scientific studies performed by the chemical manufacturer on its own product. One of the published abstracts which has appeared in scientific literature is entitled Effects of Strongarm Herbicide on Peanut Growth and Yield by J. R. Karnei, P. A. Dotray and J. W. Keeling, Texas Agricultural Experiment Station and Texas Tech University. This article was published in 2001 for research done on May 2,

2000 through harvest date November 15, 2000. This research found that in fourteen days after planting (DAP), Strongarm at 0.45 ounces per acre (oz/A) (label rate) applied preplant incorporated (PPI) or preemergence (PRE) caused injury at 28% and 40% rates. Strongarm showed injury to peanut plants at 11% preemergent and 22% preplant incorporated rates at 85 days after planting. Strongarm treatments at labeled rates for preplant incorporated showed a yield of 2,370 pounds/A as compared to the untreated acreage which yielded 3,090/A. In other words, Strongarm resulted in a 24% reduction in peanut production as compared to untreated tested acreage. The *Karnei* study concluded that Strongarm cannot be applied any earlier than five days after planting and cannot be used on soils with a pH of 7.2 or greater. Exhibit I-A. In most of the Defendant growers farms, the Strongarm was applied PPI in soil with a pH of 7.2 or greater which in my opinion caused injury to the peanuts and the growers production losses.

Another published study I rely on is Yellow Nutsedge *(Cyperus esculentus L.)* Management with Diclosulam and Metolachlor Combinations in Texas High Plains Peanut by B. L. Porter, P.A. Dotray, J. W. Keeling, and T. A. Baughman; Texas Tech University, Texas Agricultural Experiment Station, Lubbock, and Texas Cooperative Extension, Vernon. Porter, et. al. in 1999 and 2000 conducted experiments in the west Texas and found Diclosulam at labeled rates to cause injury that persisted at least 69 days after planting. The Strongarm was applied preemergent. Exhibit I-B.

Varietal Tolerance to Diclosulam and Flumioxazin in Texas Peanut by T. A. Murphree, P.A. Dotray, J. W. Keeling, B.L. Porter, T. A. Baughman, W. J. Grichar, R. G. Leon, Texas Tech University and Texas Agricultural Experiment Station, Lubbock; Texas Cooperative Extension Service, Vernon, Yoakum and College Station is a study which I rely on as a basis for my opinion.

Murphree, et. al. in 1999 and 2000 conducted experiments in west Texas and found diclosulam injury at labeled rates applied PRE. At 42 days after treatment some varieties showed as much as 45% injury. Exhibit I-C.

Another published study I rely on as a basis for my research is Weed Control and Peanut Response to Diclosulam by J. R. Karnei, P.A. Dotray, J. W. Keeling, and T. A. Baughman. Texas Tech University and Texas Agricultural Experiment Station, Lubbock, and Texas Cooperative Extension Service, Vernon. Karnei, et. al. conducted field studies in west Texas at six locations in 2000 and 2001 using both preplant incorporation (PPI) and preemergent application(PRE). Soil pH ranged from 7.6 to 8.2 and organic matter was less than 0.5% at all locations. It was concluded that PPI injured peanuts more than PRE and that PPI yield was less than PRE. Exhibit I-D.

Basically, there are 10 new restrictions in the 2001 supplemental label for Texas **that were not in the 2000 label** that would impact the use of Strongarm on all west Texas peanut operations. In fact, the new label recommendations would prevent most growers from using Strongarm. The most important is a recognition that Strongarm should not be applied on soils with a pH greater than 7.2. This would include most of west Texas peanut fields. West Texas farmers were not made aware of this precaution prior to their 2000 Strongarm applications. Since their soils are above a pH of 7.2 it can be concluded that unacceptable injury would have resulted from exposure to Strongarm. The other new label precautions are important in explaining why west Texas peanut crops were injured in 2000.

The second major label change was the elimination of Pre-Plant Incorporation PPI and more strict application recommendations on preemergence PRE applications that read: "Apply Strongarm at the rate of 0.45 oz as a preemergence application from no less than 5 days after

planting through "at cracking." Many of the west Texas farms reported peanut injury with preplant incorporation.

Exhibit 7 is a true copy of the year 2000 label from the Strongarm used by Defendant growers.

Exhibit 8 is a true copy of the year 2001 label with the significant changes highlighted.

Dow AgroSciences LLC scientific employee John M. Zabik published a report entitled Terrestrial Field Dissipation of Diclosulam at Four Sites in the United States which discusses the mobility of diclosulam in various types of soils as it is related to soil pH and other soil factors. Exhibit 9 is a true and correct copy of this published report which appeared in the Journal of Agricultural Food Chemistry, 2001, Volume 41, pages 3284-3290. I rely on this published study to show that Dow AgroSciences LLC scientists who were studying diclosulam were familiar with the effect of soil pH on diclosulam.

Another published study on which I rely is Exhibit 10, Degradation of a Sulfonamide Herbicide as a Function of Soil Sorption, Weed Research, 1992, Volume 32, pages 197-205 authored by R. G. Lehmann, J. R. Miller, D. D. Fontaine, D. A. Laskowski, J. H. Hunter and R. C. Cordes, each of whom were employed as scientists by Dow Elanco, Indianapolis, Indiana demonstrates that Dow AgroSciences LLC scientist were aware and had studied the effects of soil sorption as it relates to soil pH for sulfonamide herbicides (the same family as diclosulam/Strongarm). Their basic finding was that the higher soil pH, the more available the herbicide was to the plant. Dow AgroSciences LLC's sales representatives misrepresented the characteristics, uses or benefits of Strongarm by stating that it was a good, superior or excellent herbicide for use in west Texas peanut fields when Dow AgroSciences LLC's own scientist were aware of the increased herbicidal activity Strongarm has in the

presence of pH soils of 7.0 or greater which are the soil types in each of the Defendant growers peanut fields.

CONCLUSIONS

Based upon my review of the scientific literature Exhibits l-A, l-B, 1-C, 1-D together with my review of Dow AgroSciences LLC 2000 label for Strongarm Exhibit 7 and 2001 Supplemental Label for Strongarm Exhibit 8 together with my education, training and experience in the mode of action of herbicides and my review of the photographs and videotape of the Defendant growers peanut plants in the year 2000 and my understanding of the soil pH in the Defendant growers' peanut fields being a pH of 7.0 or greater, including the published studies in Exhibit 9 and Exhibit 10, I have the following opinions:

It is my opinion that it was negligence for Dow AgroSciences LLC to develop, test, manufacture, produce, and promote Strongarm for use in west Texas to the Defendant growers in the year 2000 because of the increased herbicidal activity Strongarm has in the presence of pH soils of 7.0 or greater which are in each of the Defendant growers peanut fields.

It is my opinion that Strongarm was not reasonably fit as a peanut crop herbicide in west Texas because of the increased herbicidal activity Strongarm has in the presence of pH soils of 7.0 or greater which are the soil types in each of the Defendant growers peanut fields.

It is my opinion that Strongarm was not merchantable as a peanut crop herbicide in west Texas because of the increased herbicidal activity Strongarm has in the present of pH soils of 7.0 or greater which are the soil types in each of the Defendant growers peanut fields.

It is my opinion that Dow AgroSciences LLC's sales representatives misrepresented the characteristics, uses or benefits of Strongarm by stating that it was a good, superior or excellent herbicide for use in west Texas

peanut fields when Dow AgroSciences LLC's own scientists were aware of the increased herbicidal activity Strongarm has in the presence of pH soils of 7.0 or greater which are the soil types in each of the Defendant growers peanut fields as demonstrated in Exhibits 9 and 10.

It is also my opinion that when Dow AgroSciences LLC's representatives states that Strongarm was a good, superior or excellent herbicide for use in west Texas peanut fields that this was a misrepresentation of the particular standard, quality or grade of Strongarm because of the increased herbicidal activity Strongarm has in the presence of pH soils of 7.0 or greater which are the types of soils on each of the Defendant growers peanut fields.

It is my opinion that Strongarm was defective as a herbicide for use in west Texas peanut fields with a soil pH of 7.0 or greater and that the defect in the product rendered the herbicide unreasonably dangerous and was producing cause of damages to each of the peanut growers because of the increased herbicidal activity Strongarm has in the presence of pH soils of 7.0 or greater which are in each of the Defendant growers' peanut fields.

It is my opinion that any statement made by Dow AgroSciences LLC or its sales representatives to the effect that Strongarm was a good, superior or excellent herbicide for use in west Texas peanut fields was a misrepresentation about Strongarm because of the increased herbicidal activity Strongarm has in the presence of pH soils of 7.0 or greater which will cause injury to peanut plants.

It is my opinion as a plant horticulturist that the use of Strongarm in the year 2000 in the west Texas peanut crops of the Defendant growers resulted in plant injury due to delayed crop development resulting in lost yield and production. Scientific studies including Exhibits 1-A through 1-D and Exhibit 9 and 10 have illustrated

problems with Strongarm each associated with a soil pH of 7.0 or greater. Over 100 farms experienced plant injury from using Strongarm in the 2000 growing season with symptoms of plant stunting, growth delay, yellowing and late maturity to harvest with reduced yield in production. Dow AgroSciences LLC recognized these growth problems and changed the Strongarm specimen, label Exhibit 8, for the year 2001 which is, in my opinion, a recognition on Dow AgroSciences LLC's part of the injury pattern to peanut growers in west Texas. Strongarm caused residual injury and damage in the year 2000 to wheat and cotton grown on land which was treated with Strongarm in the year 2000 due the herbicide carryover effect.

Further Affiant sayeth naught."

/s/ John M. Brown

JOHN M. BROWN, PH.D.

[Notary Omitted]

TITLE: Effects of Strongarm Herbicide on peanut growth and yield.

AUTHORS: J.R. Karnei, P.A. Dotray, J.W. Keeling, Graduate Research Assistant, Associate Professor, Professor

METHODS AND MATERIALS:

Variety: Flavor Runner 458

Plot size: 4 rows by 50', 3 replications

Soil type: Amarillo fine sandy loam

O.M.: 0.7%
Sand: 73%
Silt : 10%
Clay : 17%
pH : 7.6
CEC: 10.1

Planting date: May 2, 2000

Digging date: October 23, 2000

Harvest date: November 15, 2000

Irrigation: LEPA - season total 23.25 inches

Application dates:

Springtooth harrow – prior to listing	March 29
Preemergence	May 2
Postemergence	May 24

RESULTS AND DISCUSSION:

Strongarm is a new herbicide that was registered in peanut in 2000. Previous research has shown that Strongarm controls pigweed, devil's-claw, and morningglory species.

Peanut growth and yield response to Strongarm was evaluated at Ag Cares in Lamesa, TX in 2000. Strongarm was applied preplant incorporated (PPI) and preemergence (PRE) at 0.30 (2/3X), 0.45 (1X), and 0.90 (2X) oz/A. Cadre, Valor, and an untreated check were used for comparison. All plots were kept weed-free season long. At 14 days after planting (DAP), Strongarm at 1X

applied PPI or PRE injured peanut 28%, Strongarm at 2/3X PPI or PRE injured peanut 10-12%, and Strongarm at 2X applied PPI or PRE injured peanut 50%. No peanut injury was observed from Valor PRE at 3 oz/A. Strongarm at 1X injured peanut 11% PRE and 22% PPI at 85 DAP. Strongarm at 2/3X rate applied PRE and PPI injured peanut 3% and 12%, respectively at 85 DAP. Strongarm at 2X injured peanut 35% PRE and 45% PPI and Cadre injured peanut 7% 85 DAP. At the end of the season, 8 to 10% peanut injury was observed from Strongarm at the 2X rate. All other Strongarm treatments had <3% injury at the end of season. Strongarm applied PPI decreased yield 680 to 1350 lb/A compared to the non-treated plot. Less injury was observed from Strongarm PRE at 1X and 2X. Because of the injury concern, the Strongarm label has been changed for 2001, Strongarm cannot be applied any earlier than 5 days after planting, and cannot be used on soils with a pH of 7.2 or greater.

Table 1. Peanut growth and yield as affected by Strongarm treatment.

Treatment Name	Rate oz/A	Application Method	Peanut Injury (%) May 16	June 21	July 26	Sept. 8	Peanut Yield (lb/A) 2000
Strongarm	0.30	PPI	13 c	33 c	12 d	0 c	2410 b
Strongarm	0.45	PPI	28 b	40 b	22 c	3 b	2370 b
Strongarm	0.90	PPI	48 a	53 a	44 a	11a	1740 c
Strongarm	0.30	PE	10 c	22 d	3 ef	2 bc	2150 bc
Strongarm	0.45	PE	27 b	27 d	11 d	2 bc	2640 ab
Strongarm	0.90	PE	50 a	45 b	35 b	8 a	2260 bc
Cadre	1.44	PT	0 d	12 e	8 de	4 b	2430 b
COC	%v/v	PT					
Valor	3.00	PE	0 d	0 f	0 f	0 c	3070 a

YELLOW NUTSEDGE (*Cyperus esculentus* L.) MANAGEMENT WITH DICLOSULAM AND METOLACHLOR COMBINATIONS IN TEXAS HIGH PLAINS PEANUT. B.L. PORTER, P.A. DOTRAY, J.W. KEELING, and T.A. BAUGHMAN; Texas Tech University, Texas Agricultural Experiment Station, Lubbock, and Texas Cooperative Extension, Vernon.

ABSTRACT

Yellow nutsedge (*Cyperus esculentus* L.) infests numerous acres on the Texas Southern High Plains. Metolachlor has been used to control yellow nutsedge in peanut for several years. Due to concern about potential injury from preplant incorporated and preemergence applications, many growers apply metolachlor early postemergence. Experiments were conducted in 1999 and 2000 to evaluate yellow nutsedge control with dicolosulam applied PRE at four rates (0, 0.008, 0.016, and 0.024 pounds (active ingredient) per acre), metolachlor applied postemergence (POST) at four rates (0, 0.5, 1.0, and 1.3 pounds per acre), and combinations of these herbicides. Florunner peanut was planted in 2000 in a producer's field near Denver City, TX, and FlavorRunner 458 peanut was planted in a producer's field near Seminole TX in 2001 in areas heavily infested with yellow nutsedge. Applications were made using a tractor mounted compressed air sprayer that delivered 10 gallons per acre at 24 psi. Yellow nutsedge control and peanut injury was evaluated 31, 53 and 71 days after planting (DAP) in 2000 and 40, 55, and 69 DAP in 2001. Yellow nutsedge densities were counted at season's end and plots were harvested with a plot combine. Data was subjected to an analysis of variance with partitioning appropriate for a factorial arrangement. Means were separated using Fisher's Protected LSD at 0.05.

Diclosulam at 0.008, 0.016, and 0.024 lbs/A PRE controlled yellow nutsedge 47%, 62%, and 78% (71 DAP) in 2000. Metolachlor at 0.5, 1.0, and 1.3 lbs/A POST

controlled yellow nutsedge 15%, 38%, and 52% (71 DAP). A diclosulam by metolachlor interaction was observed 71 DAP. When diclosulam was applied at 0.008 lbs/A PRE, additional applications of metolachlor POST did not provide acceptable yellow nutsedge control 71 DAP. When diclosulam was applied at 0.016 lbs/A PRE, metolachlor at 1.3 lbs/A POST improved yellow nutsedge control to 88%. This control was better than metolachlor at 0.5 or 1.0 lbs/A POST, and equivalent to diclosulam 0.024 lbs/A PRE with any rate of metolachlor POST. When diclosulam was applied at 0.024 lbs/A PRE, all metolachlor POST rates provided equivalent control of yellow nutsedge (85 to 88%). End of season yellow nutsedge density was similar across herbicide combinations, with plots averaging from 0.4 to 2.5 yellow nutsedge plants per foot.[2] Untreated plots averaged 17.9 plants per foot. Metolachlor POST did not injure peanut. Diclosulam at 0.008 lbs/A injured peanut 4% 31 DAP, but no injury was observed 53 DAP in 2000. Diclosulam at 0.016 lbs/A injured peanut 11% at 31 DAP, but injury decreased to 4% at 71 DAP. Similar injury was observed from diclosulam at 0.024 lbs/A (16% at 31 DAP and 6% at 71 DAP). No injury was observed at harvest, and neither grade nor yield was affected by any herbicide treatment. Yields averaged 1,532 lbs/A.

Diclosulam at all rates controlled yellow nutsedge greater than 90% 40 and 55 DAP in 2001, but control dropped to less than 75% 69 DAP. Metolachlor at 1.0 and 1.3 lbs/A controlled yellow nutsedge greater than 75% 55 and 69 DAP. A diclosulam by metolachlor interactions was observed 69 DAP. All herbicide combinations provided acceptable control of yellow nutsedge. When diclosulam was applied at 0.008 lbs/A, metolachlor at 1.3 lbs/A controlled yellow nutsedge 95%. This control was similar to the yellow nutsedge control provided by the highest herbicide-rate combinations. When metolachlor was applied at 1.3 lbs/A, all rates of diclosulam controlled yellow nutsedge more effectively than metolachlor at 0.5 lbs/A. End of season yellow nutsedge density was similar

across herbicide combinations, with plots averaging from 0.2 to 1.6 yellow nutsedge plants per foot[2]. Untreated plots averaged 6.8 plants per foot. Metolachlor POST did not injure peanut. Diclosulam at 0.008 lbs/A did not injure peanut in 2001. Diclosulam at 0.016 lbs/A injured peanut 4% (40 DAP), and injury persisted at 69 DAP. Similar injury was observed from diclosulam at 0.024 lbs/A (12% at 40 DAP and 12% at 69 DAP). No injury was observed at harvest, and neither grade nor yield was affected by any herbicide treatment. Yields averaged 4,857 lbs/A.

VARIETAL TOLERANCE TO DICLOSULAM AND FLUMIOXAZIN IN TEXAS PEANUT

T.A. Murphree, P.A. Dotray, J.W. Keeling, B.L. Porter, T.A. Baughman, W.J. Grichar, R.G. Lemon Texas Tech University and Texas Agricultural Experiment Station, Lubbock; Texas Cooperative Extension Service, Vernon, Yoakum, and College Station

ABSTRACT

Diclosulam and flumioxazin have been reported to have broad-spectrum broadleaf weed control when applied preemergence (PRE), but some peanut injury has been observed. Peanut injury on the Texas Southern High Plains was first observed following excessive rates of diclosulam (0.048 lb/A). In 1999 injury was also observed at the 0.024 lb ai/a applied PRE, but no injury was apparent by the end of season (Karnei et al. 2000). Due to injury in 2000 from diclosulam, a peanut variety trial was conducted in Gaines County to test peanut varietal tolerance to diclosulam and flumioxazin. In addition, diclosulam application timing was also investigated. Four high oleic peanut lines: Flavor Runner 458 Sunoleic 97R, TX 977006, Georgia Hi O/L and one conventional variety, Tamrun 96, were used in this study.

Treatments were replicated three times in a split-plot design. Plot size was 7 by 30 ft. Diclosulam was applied at two rates, 0.016 and 0.024 lb ai/A, both PRE and postemergence (POST). Flumioxazin was applied PRE at 0.063 and 0.094 lb/A. Peanuts were planted and PRE treatments were applied May 15, while POST treatments were applied June 12. All treatments were applied using a CO2 backpack sprayer calibrated to deliver 10 GPA. Evaluations were made on PRE treatments 14, 42, and 118 days after treatment (DAT) while POST treatments were evaluated 14, 58 and 90 DAT. Peanut grades and yields were determined at the end of the season.

At 14 DAT diclosulam applied PRE at 0.016 and 0.024 lb ai/A injured peanut 10 to 40% in all varieties except Tamrun 96. At 42 DAT, diclosulam PRE injured Flavor Runner 458 and the Sunoleic 97R 20 to 25% while injury to Georgia Hi O/L from diclosulam at 0.024 lb ai/A was 35 to 45%. At 118 DAT, all injury decreased to < 5% and yield was not affected by diclosulam PRE. Less than 5% peanut injury was observed on all varieties from flumioxazin applied PRE at 14 DAT. No injury was observed at 42 and 118 DAT and yield was not affected by any flumioxazin treatment. At 14 DAT, diclosulam applied POST at both rates injured peanut < 5% in all varieties and no injury was observed 90 DAT. Yield was not affected by diclosulam (POST).

At the South Texas location in Yoakum, no peanut response was observed following any treatment of diclosulam and flumioxazin applied PRE. When flumioxazin was applied PRE at the Rolling Plains location in Motley County, no injury was observed to any variety, at any rate, throughout the growing season and yield was not reduced.

Future studies will be conducted to evaluate diclosulam POST and to examine factors contributing to injury caused by diclosulam and flumioxazin PRE.

WEED CONTROL AND PEANUT RESPONSE TO DICLOSULAM. J.R. Karnei, P.A. Dotray, J.W. Keeling, and T.A. Baughman. Texas Tech University and Texas Agricultural Experiment Station, Lubbock, and Texas Cooperative Extension Service, Vernon.

ABSTRACT

Field studies were conducted in West Texas at six locations in 2000 and 2001 to evaluate weed control and peanut (*Arachis hypogaea*) response to diclosulam applied preplant incorporated (PPI) and preemergence (PRE). All plots received a PPI treatment of ethalfluralin at 0.75 lb ai/A or pendimethalin at 0.50 to 0.75 lb ai/A for Palmer amaranth (*Amaranthus palmeri*) control. Diclosulam was applied PPI and PRE at 0.016 (2/3x), 0.024 (1x), and 0.048 (2x) lb ai/A. Other treatments included imazapic postemergence (POST) at 0.063 lb ai/A, flumioxazin PRE at 0.094 lb ai/A, and a non-treated check.

Weed control studies were conducted in Brownfield in 2000 and Lamesa in 2001. Diclosulam at 0.024 lb controlled purple nutsedge (*Cyperus rotundus*) 60 to 70% in 2000 and 50 to 60% (late-season) in 2001. Ivyleaf morningglory (*Ipomoea hederacea*) was controlled 60 to 70% when diclosulam was applied PPI or PRE at 0.024 lb in 2000. In 2001, diclosulam applied PPI or PRE controlled Ivyleaf morningglory > 85% early-season, and at 124 days after planting (DAP), diclosulam at 0.024 lb provided 80% (PRE) and 40% (PPI) control. Control of both weed species with diclosulam increased as rate increased for both PPI and PRE applications.

Peanut tolerance trials were conducted in Lamesa in 2000 and 2001 and in Seminole in 2001. All plots were kept weed-free throughout the season. Soil pH ranged from 7.6 to 8.2 and organic matter was less than 0.5% at all locations. At 14 DAP, diclosulam at 0.024 lb injured peanut 28 to 30% (PPI) and 17 to 27% (PRE) in both years. Diclosulam at 0.048 lb injured peanut 40 to 50%

regardless of application. Diclosulam at 0.024 lb applied PPI or PRE injured peanut less than 8% late-season. In 2000 and 2001, plots treated with diclosulam at 0.048 lb PPI produced the lowest yields. Plots treated with diclosulam at 0.024 lb PPI yielded less than plots treated with diclosulam at 0.024 lb PRE in both years. Peanut grade was not affected by any treatment when compared to the non-treated check. At Seminole, injury was less than injury observed at Lamesa early-season, and less than 10% injury was observed late-season. No differences were observed in yield or grade at Seminole.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action
	)	No. 5-01CV0331-C
DENNIS BATES, [*et al.*],	)	
	)	
Defendants.	)	

AFFIDAVIT OF TODD DENMAN

THE STATE OF TEXAS §

COUNTY OF COMANCHE §

Before me, the undersigned authority, on this day personally appeared TODD DENMAN, as Partner and Personal Representative of the Estate of Burk Denman, who being first duly sworn, made the following declaration based on personal knowledge under oath:

"I was a partner with and am now the Personal Representative of the Estate of Burk Denman, a peanut farmer in Comanche County, Texas. My father, Burk Denman, was named as a Defendant in the above referenced lawsuit. Before his death on January 6, 2002, my father and I had been partners in our peanut business for many years. After applying Strongarm® herbicide in May 13, 2000, I saw that the peanut plants which were treated with Strongarm® were not growing normally, were stunted in their growth, and were not developing foliage. As a farmer for over 20 years, I recognized each of these

growth problems as a symptom of herbicide injury. The only herbicide we had used was Strongarm®. Because of each of these growth problems, the peanut crop was significantly delayed in maturity for harvest, far beyond normal maturity. The delay in maturity caused us to incur additional crop expense in producing and harvesting the peanuts and we experienced a significant reduction in harvest profit for the year 2000. In July 2000, we contacted Ralph Porter, the area representative for Dow AgroSciences LLC, and notified him about the herbicide injury to our 2000 peanut crop. Mr. Porter, the Dow AgroSciences LLC area representative, told us that he would come out and inspect our peanuts, which he did, and he said that regardless of the outcome we needed to grow out the peanut crop to harvest. Mr. Porter went on to say that Dow would make up any loss of production to us after harvest if we would grow the crop to harvest. We relied on his representation and grew the crop to harvest. We received a letter from Greg Fletcher, Product Marketing Manager of Dow AgroSciences LLC. The letter is attached as Exhibit A to this affidavit. We did everything that Dow AgroSciences LLC asked us to do in Exhibit A and Dow AgroSciences LLC has not paid us for our year 2000 production loss as they promised to do. We relied on Dow AgroSciences LLC's representations and promises made by Mr. Porter and Greg Fletcher in Exhibit A. Because we relied on Dow AgroSciences LLC's representations and promises, my father and I spent substantial additional money for additional chemical inputs, water, labor, electricity and equipment time in growing the crop to harvest that we would not have spent except for the representations and promises of Dow AgroSciences LLC, which we relied on, that they would pay us for the loss of production that we had for the 2000 crop. The Strongarm® was defective as a herbicide and did not perform as a herbicide should which caused injury and money damages to the peanut crop.

When we purchased the Strongarm®, the package insert with all the information about the product was sealed in plastic and could not be opened until after the Strongarm® was purchased. After purchasing the Strongarm® I opened the sealed package insert to read the application instructions. I read the package insert and did not see any written information about risks of using Strongarm® or limitations of claims against Dow AgroSciences LLC if the Strongarm® did not perform or caused crop injury. After we used the Strongarm® and it had caused noticeable crop injury, I read the package insert again. The package insert is Exhibit B attached to this affidavit. On this reading I noticed for the first time the paragraph entitled Inherent Risks of Use on page 10 of the package insert and the paragraph entitled Limitations of Remedies on page 11. The package insert is numbered page 1 through 11 with an unnumbered first page. The one paragraph of information on page 10 entitled Inherent Risks of Use is not conspicuous because the print is the smallest print on the page, the print is all the same size with no capital letters or bold letters and the print is all the same color. It is my belief that the reason that I did not see and appreciate the paragraph entitled Inherent Risks of Use is because the paragraph as on page 10 of the package insert because the print is the smallest because the print size on the page and in the entire package insert, because the print is all the same small size without any bold letters or capital letters or in different colors.

The one paragraph of information on page 11 entitled Limitations of Remedies is not conspicuous because the print is all the same size with no capital letters or bold letters and the print is all the same color. It is my belief that the reason that I did not see and appreciate the paragraph entitled Limitations of Remedies is because the paragraph was on page 11 of the package insert because the print is the smallest print size on the page and in the entire package insert, because the print is all the same

small size without any bold letters or capital letters or in different colors.

I do not know what the package insert meant when it stated that Dow AgroSciences LLC is not liable for consequential or incidental damages or losses. The terms consequential or incidental damages or losses were not defined in the package insert Exhibit B.

My lawyer tells me that the legal definition of consequential damages is "*Such damage, loss or injury as does not flow directly and immediately from the act of the party, but only from some of the consequences or results of such act. Damages which arise from intervention of special circumstances not ordinarily predictable. Those losses or injuries which are a result of an act but are not direct and immediate. Consequential damages resulting from a seller's breach of contract include any loss resulting from general or particular requirements and needs of which the seller at the time of contracting had reason to know and which could not reasonably be prevented by cover or otherwise, and injury to person or property proximately resulting from any breach of warranty.* U.C.C. § 2-715(2)." (Black's Law Dictionary, Sixth Edition).

My lawyer tells me that the legal definition of incidental damages is *"Under U.C.C. § 2-710, such damages include any commercially reasonable charges, expenses or commissions incurred in stopping delivery, in the transportation, care and custody of goods after the buyer's breach, in connection with the return or resale of the goods otherwise resulting from the breach. Also, such damages, resulting from a seller's breach of contract, include expenses reasonably incurred in inspection, receipt, transportation and care and custody of goods rightfully rejected, any commercially reasonable charges, expenses or commissions in connection with effecting cover and any other reasonable expense incident to the delay or other breach.* U.C.C. § 2-715(1)." (Black's Law Dictionary, Sixth Edition).

If I had known that Dow AgroSciences LLC was saying it would not pay me for all my expenses and lost profit if the Strongarm® caused injury to my peanut crop, I would not have bought or used the Strongarm® on my peanut crop in 2000.

My father and I used Strongarm® on our peanuts in 2000 after it was recommended to us by our local chemical distributor and the local Dow AgroSciences LLC representative.

Further Affiant sayeth naught."

/s/ Todd Denman

TODD DENMAN, Partner and
Personal Representative of the
Estate of Burk Denman

[Notary Omitted]

[Exhibit A]

Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268

[Company Logo Omitted]

December 5, 2000
Mr. Burk Denman
Route 1 Box 71
Carlton, TX 76442

In response to your concerns regarding potential effects of Strongarm* herbicide on your 2000 peanut crop, Dow AgroSciences initiated an effort to evaluate and understand the issues affecting the current production season in the southwest. In trying to determine why peanut yield reductions occurred in the southwest this year, Dow AgroSciences is reviewing and considering, among other things, the use of Strongarm herbicide, plant disease and physiology, weather, soil, water quality and quantity, weed control, crop condition at harvest, and post-digging conditions.

In that connection, Dow AgroSciences has retained the services of Rush, Marcroft and Associates, a group of independent agricultural consultants specializing in crop loss evaluations. Dale Rush, Ph.D., along with Ed Sieckert, M.S. and Neil Phillips, Sr., have agreed to serve as neutral, third-party mediators to work to facilitate fair and mutually-agreeable resolutions of lost yield claims. They have also agreed to evaluate the agronomic issues for each field/circle and to provide an economic analysis after considering the contribution of all relevant factors to yield reduction, if any occurred.

In this capacity, Dr. Rush and associates have agreed to try to negotiate a mutually agreeable settlement between you and Dow AgroSciences. The mediation process is not binding on either you or Dow AgroSciences unless a

settlement agreement is reached. If Dr. Rush and associates are able to work with you and Dow AgroSciences to achieve an acceptable settlement, then you will be asked to sign a settlement agreement recognizing that all of your 2000 peanut crop claims against Dow AgroSciences have been settled. If Dr. Rush and his associates are not able to work out a settlement to which both you and Dow AgroSciences agree, then you are free to pursue any and all other legal remedies available to you if you wish to do so.

If you wish to participate in the claim evaluation and mediation process, you must do two things:

(1) Complete and return the enclosed questionnaire to Dr. Rush, along with other documentation requested; and

(2) Sign the bottom of this letter and return a copy of it to Dr. Rush.

Signing the bottom of this letter and returning it to Dr. Rush signifies that you have read about the mediation process, that you understand how it will work, and that you agree to participate in the mediation process as explained in this letter.

In addition to the questionnaire, Dr. Rush would also find helpful any documents you can give him to help assess yield and quality factors so as to allow comparison with your peanut production history. Because the effects of prolonged drought conditions contributed to yield reductions associated with temperature stress, irrigation water quality, quantity, and soil salinity, Dr. Rush would like to have historical irrigation data including power utility records for the specific locations, in order to compare irrigation requirements where you have grown peanuts in the recent past.

Dow AgroSciences plans to review all claims, including yours, submitted in connection with crop losses allegedly

caused by Strongarm during the 2000 growing season. However, please be advised that the label for Strongarm specifically provides that Dow AgroSciences is not liable for "losses or damages resulting from handling or use" of Strongarm unless Dow AgroSciences has been "promptly notified" of such loss or damage. Dow AgroSciences insists upon prompt notice of loss or damage claims so that it is able to properly investigate and evaluate product performance, and to isolate causative factors in order to provide timely assistance and corrective recommendations.

Once you return the questionnaire, your signed copy of this letter, and any other documents listed above, Dr. Rush and associates will begin reviewing your information along with the data Dow AgroSciences already has collected during the 2000 growing season. They will then work with both you and Dow AgroSciences in an effort to settle your claims.

A pre-addressed envelope is included to aid in returning the necessary information. Please keep copies of all submitted information for you own records. Please return the information requested no later than **December 23, 2000**.

If you have contacted or decide to contact a lawyer in connection with your claim against Dow AgroSciences, please forward this letter to your lawyer immediately. You are free to participate in the mediation process even if you have a lawyer, but please be advised that your lawyer will need to facilitate any and all future contacts and communication with Dow AgroSciences.

Thank you for your cooperation in this matter.

/s/ Greg Fletcher
Greg Fletcher
Product Marketing Manager

Mail to:
Dale W. Rush, Ph.D.
Rush, Marcroft and Associates
28951 Falcon Ridge Road
Salinas, CA 93908

/s/ Burk Denman
Grower Signature

12/20/00
Date

[Exhibit B reproduced at pp. 165-178, *infra*]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action
	)	No. 5-01CV0331-C
DENNIS BATES, [*et al.*],	)	
	)	
Defendants.	)	

AFFIDAVIT OF NEIL FRIESEN

THE STATE OF TEXAS §
COUNTY OF GAINES §

Before me, the undersigned authority, on this day personally appeared NEIL FRIESEN, who being first duly sworn, made the following declaration under oath:

"My name is Niel Friesen. I am an adult, over the age of 21 years and I am competent to testify as to all matters stated herein.

I am a farmer and I am one of the Defendants in the above styled and numbered lawsuit.

I am familiar with the facts and circumstances discussed herein and make the following declaration based on personal knowledge.

I attended a Field Day in 1999 sponsored by an area chemical company concerning Strongarm® herbicide. We were told that Strongarm® was an excellent herbicide to use for weed control on West Texas peanuts. We were told that Strongarm® could be applied at planting time by

incorporating Strongarm® into the soil with the peanut seed. I relied upon the representations about Strongarm® which I heard at the Field Day.

After applying Strongarm® herbicide, I noticed that the peanut plants which were treated with Strongarm® were not growing normally, were stunted in their growth, were yellowed and discolored and were not developing foliage. I also noted that the peanut plants did not have feeder roots. As a farmer, I recognize each of these growth problems as a symptom of herbicide injury. The only herbicide that I had used on these peanuts was Strongarm®. Because of these growth problems, the peanut crop was significantly delayed in maturity for harvest, far beyond normal maturity. The delay in maturity caused me to incur additional crop expense in producing and harvesting the peanuts and I experienced a significant reduction in harvest profit for the year 2000.

On or about July, 2000, I called Robert Armstrong, sales manager at Agriplex West, my chemical distributor and local representative for Dow AgroSciences, L.L.C., and notified him about the injury to my 2000 peanut crop. Gregg Alpers, area representative for Dow AgroSciences, L.L.C., told me that he would come out and inspect my peanuts and that regardless of the outcome I needed to grow out the peanut crop to harvest. Mr. Alpers went on to say that Dow would make up any loss of production to me after harvest.

I used Strongarm® on my peanuts in 2000 after it was recommended to me by my local chemical distributor and the local Dow AgroSciences, L.L.C. representative.

When I purchased the Strongarm®, the package insert with all the information about the product was sealed in plastic and could not be opened until after the Strongarm® was purchased. After purchasing the Strongarm®, I opened the sealed package insert to read the application instructions. I read the package insert

about the application instructions and did not see any written information about the risks of using Strongarm® or limitations of claims against Dow Agrosciences if the Strongarm® did not perform or cause crop injury. After I used the Strongarm®, I noticed considerable crop injury and I read the package insert again. The package insert is Exhibit "1" attached to this Affidavit. On this reading, I noticed for the first time the paragraph entitled "Inherent Risks of Use" on page 10 of the package insert and the paragraph entitled "Limitations of Remedies" on page 11. The package insert is 4.5 inches by 4.5 inches and is numbered page 1 through page 11 with an unnumbered first page. The one paragraph with information on page 10 entitled "Inherent Risks of Use" is not conspicuous to me because the print is the smallest print on the page, all of the print is the same size with no capital letters or bold letters and the print is all the same color. It is my belief that the reason I did not see the paragraph entitled "Inherent Risks of Use" is because the paragraph was on page 10 of the package insert and because the print is the smallest print size on the page and in the entire package insert and because the print is the same small size without any bold letters or capital letters or in different colors.

The one paragraph of information on page 11 entitled "Limitations of Remedies" is not conspicuous because the print is all the same size with no capital letters or bold letters and the print is all the same color. It is my belief that the reason I did not see and appreciate the paragraph entitled "Limitations of Remedies" is because the paragraph was on page 11, which was the last page of the package insert, because the print is the smallest print size on the page and in the entire package insert, and because the print is all the same small size without any bold letters or capital letters or in different colors.

Further, My lawyer tells me that the legal definition of consequential damages is "*Such damage, loss or injury*

as does not flow directly and immediately from the act of the party, but only from some of the consequences or results of such act. Damages which arise from intervention of special circumstances not ordinarily predictable. Those losses or injuries which are a result of an act but are not direct and immediate. Consequential damages resulting from a seller's breach of contract include any loss resulting from general or particular requirements and needs of which the seller at the time of contracting had reason to know and which could not reasonably be prevented by cover or otherwise, and injury to person property proximately resulting from any breach of warranty. U.C.C.§ 2-715(2)." (Black's Law Dictionary, Sixth Edition).

My lawyer tells me that the legal definition of incidental damages is "*Under U.C.C. § 2-710, such damages including any commercially reasonable charge, expenses or commissions incurred in stopping delivery, in the transportation, care and custody of goods after the buyer's breach, in connection with the return or resale of the goods otherwise resulting from the breach. Also, such damages, resulting from a seller's breach of contract, include expenses reasonably incurred in inspection, receipt, transportation and care and custody of goods rightfully rejected, any commercially reasonable charges, expenses or commissions in connection with effecting cover and any other reasonable expense incident to the delay or other breach.* U.C.C. § 2-715(1)." (Black's Law Dictionary, Sixth Edition).

If I had know that Dow Agrosciences in the package insert was saying it would not pay me for all of my expenses and any loss profit if the Strongarm® caused injury to my peanut crop, I would not have bought or used the Strongarm® on my peanut crop in 2000.

FURTHER AFFIANT SAYETH NOT."

Witness my hand this 1st day of April, 2002.

/s/ Neil Friesen
NEIL FRIESEN

[Notary Omitted]

[Exhibit 1 reproduced at pp. 165-178, *infra*]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action
	)	No. 5-01CV0331-C
DENNIS BATES, [*et al.*],	)	
	)	
Defendants.	)	

AFFIDAVIT OF THOMAS R. FUSTON

STATE OF §

COUNTY OF HALL §

On this day appeared **THOMAS R. FUSTON**, being duly sworn, stated on his oath as follows:

My name is Thomas R. Fuston. I am an adult, over the age of 21 years and I am competent to testify as to all matters stated herein.

I am a farmer and I am one of the Defendants in the above styled and numbered lawsuit.

I am familiar with the facts and circumstances discussed herein and make the following declaration based on personal knowledge.

In the year 2000, I attended a grower's meeting sponsored by Valley Peanut Growers and Dow Agrosciences, LLC concerning Strongarm® herbicide. The Dow representative said that Strongarm® was an excellent herbicide to use in West Texas soil for peanuts and weed control. He said that Strongarm® was less

expensive than Cadre which was another herbicide that many of the growers had been using. He said that Strongarm® could be applied at planting time by incorporating Strongarm® into the soil with the peanut seed. After listening to what he said, I relied on his representations about Strongarm® and purchased and applied the Strongarm®.

After applying Strongarm® herbicide, I noticed that the peanut plants which were treated with Strongarm® were not growing normally, were stunted in their growth, were yellowed and discolored and were not developing foliage. I also noted that the peanut plants did not have feeder roots. As a farmer, I recognize each of these growth problems as a symptom of herbicide injury. The only herbicide that I had used on these peanuts was Strongarm®. Because of these growth problems, the peanut crop was significantly delayed in maturity for harvest, far beyond normal maturity. The delay in maturity caused me to incur additional crop expense in producing and harvesting the peanuts and I experienced a significant reduction in harvest profit for the year 2000.

After I noticed the injury to my peanut crop, I called Jodie Stockett, the area representative for Dow and notified her about the injury to my 2000 peanut crop. She told me that she would come out and inspect my peanuts and that regardless of the outcome, I needed to grow the peanut crop to harvest which would mean that I should continue to raise the crop through to harvest. She told me that Dow would make up any lost production that I had in the harvest. I relied on these promises and grew the crop out to harvest and had a substantial loss of production and additional expenses.

When I purchased the Strongarm®, the package insert with all the information about the product was sealed in plastic and could not be opened until after the Strongarm® was purchased. After purchasing the Strongarm®, I opened the sealed package insert to read

the application instructions. I read the package insert about the application instructions and did not see any written information about the risks of using Strongarm® or limitations of claims against Dow Agrosciences if the Strongarm® did not perform or cause crop injury. After I used the Strongarm®, I noticed considerable crop injury and I read the package insert again. The package insert is Exhibit "1" attached to this Affidavit. On this reading, I noticed for the first time the paragraph entitled "Inherent Risks of Use" on page 10 of the package insert and the paragraph entitled "Limitations of Remedies" on page 11. The package insert is 4.5 inches by 4.5 inches and is numbered page 1 through page 11 with an unnumbered first page. The one paragraph with information on page 10 entitled "Inherent Risks of Use" is not conspicuous to me because the print is the smallest print on the page, all of the print is the same size with no capital letters or bold letters and the print is all the same color. It is my belief that the reason I did not see the paragraph entitled "Inherent Risks of Use" is because the paragraph was on page 10 of the package insert and because the print is the smallest print size on the page and in the entire package insert and because the print is the same small size without any bold letters or capital letters or in different colors.

The one paragraph of information on page 11 entitled "Limitations of Remedies" is not conspicuous because the print is all the same size with no capital letters or bold letters and the print is all the same color. It is my belief that the reason I did not see and appreciate the paragraph entitled "Limitations of Remedies" is because the paragraph was on page 11, which was the last page of the package insert, because the print is the smallest print size on the page and in the entire package insert, and because the print is all the same small size without any bold letters or capital letters or in different colors.

When I read the package insert the second time, I saw the language about Dow Agrosciences not being liable for consequential or incidental damages or losses. The terms consequential or incidental damages or losses are not defined in the package insert and I had no idea what they meant.

My lawyer tells me that the legal definition of consequential damages is "*Such damage, loss or injury as does not flow directly and immediately from the act of the party, but only from some of the consequences or results of such act. Damages which arise from intervention of special circumstances not ordinarily predictable. Those losses or injuries which are a result of an act but are not direct and immediate. Consequential damages resulting from a seller's breach of contract include any loss resulting from general or particular, requirements and needs of which the seller at the time of contracting had reason to know and which could not reasonably be prevented by cover or otherwise, and injury to person or property proximately resulting from any breach of warranty.* U.C.C. § 2-715(2)." (Black's Law Dictionary, Sixth Edition).

My lawyer tells me that the legal definition of incidental damages is *"Under U.C.C. § 2-710, such damages including any commercially reasonable charge, expenses or commissions incurred in stopping delivery, in the transportation, care and custody of goods after the buyer's breach, in connection with the return or resale of the goods otherwise resulting from the breach. Also, such damages, resulting from a seller's breach of contract, include expenses reasonably incurred in inspection, receipt, transportation and care and custody of goods rightfully rejected, any commercially reasonable charges, expenses or commissions in connection with effecting cover and any other reasonable expense incident to the delay or other breach.* U.C.C. § 2-715 (1)." (Black's Law Dictionary, Sixth Edition).

If I had know that Dow Agrosciences in the package insert was saying it would not pay me for all of my expenses and any loss profit if the Strongarm® caused injury to my peanut corp, I would not have bought or used the Strongarm® on my peanut crop in 2000.

FURTHER AFFIANT SAYETH NOT." Witness my hand this 29 day of March, 2002.

/s/ Thomas R. Fuston
THOMAS R. FUSTON

[Notary Omitted]

[Exhibit 1 reproduced at pp. 165-178, *infra*]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action
	)	No. 5-01CV0331-C
DENNIS BATES, [*et al.*],	)	
	)	
Defendants.	)	

AFFIDAVIT OF STACY LEE PRICE

STATE OF §
COUNTY OF HALL §

On this day appeared **STACY LEE PRICE**, being duly sworn, stated on his oath as follows:

My name is Stacy Lee Price. I am an adult, over the age of 21 years and I am competent to testify as to all matters stated herein.

I am a farmer and I am one of the Defendants in the above styled and numbered lawsuit.

I am familiar with the facts and circumstances discussed herein and make the following declaration based on personal knowledge.

In the year 2000, I attended a grower's meeting sponsored by Valley Peanut Growers and Dow Agrosciences, LLC concerning Strongarm® herbicide. The Dow representative said that Strongarm® was an excellent herbicide to use in West Texas soil for peanuts

and weed control. He said that Strongarm® was less expensive than Cadre which was another herbicide that many of the growers had been using. He said that Strongarm® could be applied at planting time by incorporating Strongarm® into the soil with the peanut seed. After listening to what he said, I relied on his representations about Strongarm® and purchased and applied the Strongarm®.

After applying Strongarm® herbicide, I noticed that the peanut plants which were treated with Strongarm® were not growing normally, were stunted in their growth, were yellowed and discolored and were not developing foliage. I also noted that the peanut plants did not have feeder roots. As a farmer, I recognize each of these growth problems as a symptom of herbicide injury. The only herbicide that I had used on these pea nuts was Strongarm®. Because of these growth problems, the peanut crop was significantly delayed in maturity for harvest, far beyond normal maturity. The delay in maturity caused me to incur additional crop expense in producing and harvesting the peanuts and I experienced a significant reduction in harvest profit for the year 2000.

When I purchased the Strongarm®, the package insert with all the information about the product was sealed in plastic and could not be opened until after the Strongarm® was purchased. After purchasing the Strongarm®, I opened the sealed package insert to read the application instructions. I read the package insert about the application instructions and did not see any written information about the risks of using Strongarm® or limitations of claims against Dow Agrosciences if the Strongarm® did not perform or cause crop injury. After I used the Strongarm®, I noticed considerable crop injury and I read the package insert again. The package insert is Exhibit "1" attached to this Affidavit. On this reading, I noticed for the first time the paragraph entitled "Inherent Risks of Use" on page 10 of the package insert and the

paragraph entitled "Limitations of Remedies" on page 11. The package insert is 4.5 inches by 4.5 inches and is numbered page 1 through page 11 with an unnumbered first page. The one paragraph with information on page 10 entitled "Inherent Risks of Use" is not conspicuous to me because the print is the smallest print on the page, all of the print is the same size with no capital letters or bold letters and the print is all the same color. It is my belief that the reason I did not see the paragraph entitled "Inherent Risks of Use" is because the paragraph was on page 10 of the package insert and because the print is the smallest print size on the page and in the entire package insert and because the print is the same small size without any bold letters or capital letters or in different colors.

The one paragraph of information on page 11 entitled "Limitations of Remedies" is not conspicuous because the print is all the same size with no capital letters or bold letters and the print is all the same color. It is my belief that the reason I did not see and appreciate the paragraph entitled "Limitations of Remedies" is because the paragraph was on page 11, which was the last page of the package insert, because the print is the smallest print size on the page and in the entire package insert, and because the print is all the same small size without any bold letters or capital letters or in different colors.

When I read the package insert the second time, I saw the language about Dow Agrosciences not being liable for consequential or incidental damages or losses. The terms consequential or incidental damages or losses are not defined in the package insert and I had no idea what they meant.

My lawyer tells me that the legal definition of consequential damages is *"Such damage, loss or injury as does not flow directly and immediately from the act of the party, but only from some of the consequences or results of such act. Damages which arise from intervention of special*

circumstances not ordinarily predictable. Those losses or injuries which are a result of an act but are not direct and immediate. Consequential damages resulting from a seller's breach of contract include any loss resulting from general or particular requirements and needs of which the seller at the time of contracting had reason to know and which could not reasonably be prevented by cover or otherwise, resulting from any breach of warranty. U.C.C. § 2-715(2)." (Black's Law Dictionary, Sixth Edition).

My lawyer tells me that the legal definition of incidental damages is *"Under U.C.C. § 2-710, such damages including any commercially reasonable charge, expenses or commissions incurred in stopping delivery, in the transportation, care and custody of goods after the buyer's breach, in connection with the return or resale of the goods otherwise resulting from the breach. Also, such damages, resulting from a seller's breach of contract, include expenses reasonably incurred in inspection, receipt, transportation and care and custody of goods rightfully rejected, any commercially reasonable charges, expenses or commissions in connection with effecting cover and any other reasonable expense incident to the delay or other breach.* U.C.C. § 2-715 (1)." (Black's Law Dictionary, Sixth Edition).

If I had know that Dow Agrosciences in the package insert was saying it would not pay me for all of my expenses and any loss profit if the Strongarm® caused injury to my peanut corp, I would not have bought or used the Strongarm® on my peanut crop in 2000.

FURTHER AFFIANT SAYETH NOT." Witness my hand this 29 day of March, 2002.

/s/ Stacy Lee Price
STACY LEE PRICE

[Notary Omitted]

[Exhibit 1 reproduced at pp. 165-178, *infra*]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action
	)	No. 5-01CV0331-C
DENNIS BATES, [*et al.*],	)	
	)	
Defendants.	)	

AFFIDAVIT OF ARTHUR GALVAN

THE STATE OF TEXAS §
COUNTY OF YOAKUM §

Before me, the undersigned authority, on this day personally appeared ARTHUR GALVAN, who being first duly sworn, made the following declaration under oath:

"I am a peanut farmer in Yoakum County, Texas. I am a party in the above referenced lawsuit. I purchased Strongarm® herbicide manufactured by Dow AgroSciences LLC from West Texas Agriplex located in Seminole, Texas in May, 2000. I applied the Strongarm® as I was planting my peanuts on my own farm and the G-5 partnership farm. After the peanuts came up, they were very weak, were not growing normally, were stunted in their growth and were nor properly developing foliage. I recognized each of these growth problems as a system of herbicide injury. The only herbicide I had used on the crop was Strongarm®. I contacted Gregg Alpers, area representative for Dow AgroSciences, L.L.C., and notified him about the injury to my 2000 peanut crop. He came

out and examined my peanuts. He told that if I would go ahead and grow the crop to maturity and harvest that the peanuts would grow out of the problems. He also told me that Dow AgroSciences LLC would make up any loss of production to me after the harvest. I relied upon his representation and promise and grew the crop to harvest. Dow AgroSciences LLC has not paid me for the year 2000 production loss as they promised to do. I relied on Dow AgroSciences LLC's representations and promises made to me by Mr. Alpers. Because I relied on Dow AgroSciences LLC's representations and promises, I spent substantial additional money for additional chemical inputs, water, labor, electricity and equipment time in growing the crop to harvest that I would not have spent except for the representations and promises of Dow AgroSciences LLC which I relied on, that they would pay me for the loss of production, if any, that I had for the year 2000 crop. The Strongarm® was defective as a herbicide and did not perform as a herbicide should and caused injury and money damages to my peanut crop.

I used Strongarm® on my peanuts in 2000 after it was recommended to me by my local chemical distributor West Texas Agriplex and the local Dow AgroSciences LLC representative.

When I purchased the Strongarm®, the package insert with all the information about the product was sealed in plastic and could not be opened until after the Strongarm® was purchased. After purchasing the Strongarm®, I opened the sealed package insert to read the application instructions. I read the package insert about the application instructions and did not see any written information about the risks of using Strongarm® or limitations of claims against Dow Agrosciences if the Strongarm® did not perform or cause crop injury. After I used the Strongarm®, I noticed considerable crop injury and I read the package insert again. The package insert is Exhibit "1" attached to this Affidavit. On this reading, I

noticed for the first time the paragraph entitled "Inherent Risks of Use" on page 10 of the package insert and the paragraph entitled "Limitations of Remedies" on page 11. The package insert is 4.5 inches by 4.5 inches and is numbered page 1 through page 11 with an unnumbered first page. The one paragraph with information on page 10 entitled "Inherent Risks of Use" is not conspicuous to me because the print is the smallest print on the page, all of the print is the same size with no capital letters or bold letters and the print is all the same color. It is my belief that the reason I did nor see the paragraph entitled "Inherent Risks of Use" is because the paragraph was on page 10 of the package insert and because the print is the smallest print size on the page and in the entire package insert and because the print is the same small size without any bold letters or capital letters or in different colors.

The one paragraph of information on page 11 entitled "Limitations of Remedies" is not conspicuous because the print is all the same size with no capital letters or bold letters and the print is all the same color. It is my belief that the reason I did not see and appreciate the paragraph entitled "Limitations of Remedies" is because the paragraph was on page 11, which was the last page of the package insert, because the print is the smallest print size on the page and in the entire package insert, and because the print is all the same small size without any bold letters or capital letters or in different colors.

When I read the package insert the second time, I saw the language about Dow Agrosciences not being liable for consequential or incidental damages or losses. The terms consequential or incidental damages or losses are not defined in the package insert and I had no idea what they meant.

My lawyer tells me that the legal definition of consequential damages is "*Such damage, loss or injury, as does not flow directly and immediately from the act of the party, but only from some of the consequences or results of*

such act. Damages which arise from intervention of special circumstances not ordinarily predictable. Those losses or injuries which are a result of an act but are not direct and immediate. Consequential damages resulting from a seller's breach of contract include any loss resulting from general or particular requirements and needs of which the seller at the time of contracting had reason to know and which could not reasonably be prevented by cover or otherwise, and injury to person or property proximately resulting from any breach of warranty. U.C.C § 2-715(2)." (Black's Law Dictionary, Sixth Edition).

My lawyer tells me that the legal definition of incidental damages is "*Under U.C.C § 2-710, such damages including any commercially reasonable charge, expenses or commissions incurred in stopping delivery, in the transportation, care and custody of goods after the buyer's breach, in connection with the return or resale of the goods otherwise resulting from the breach. Also, such damages, resulting from a seller's breach of contract, include expenses reasonably incurred in inspection, receipt, transportation and care and custody of goods rightfully rejected, any commercially reasonable charges, expenses or commissions in connection with effecting cover and any other reasonable expense incident to the delay or other breach.* U.C.C. § 2-715(1)." (Black's Law Dictionary, Sixth Edition).

If I had know that Dow Agrosciences in the package insert was saying it would not pay me for all of my expenses and any loss profit if the Strongarm® caused injury to my peanut corp, I would not have bought or used the Strongarm® on my peanut crop in 2000.

FURTHER AFFIANT SAYETH NOT." Witness my hand this 29 day of March, 2002.

/s/ Arthur Galvan
ARTHUR GALVAN

[Notary Omitted]

EDITOR'S NOTE

THE FOLLOWING PAGES WERE POOR HARD COPY AT THE TIME OF FILMING. IF AND WHEN A BETTER COPY CAN BE OBTAINED, A NEW FICHE WILL BE ISSUED.

Dow AgroSciences™

Strongarm*

For Broadleaf Weed Control in Peanuts

Active Ingredients:	
diclosulam: N-(2,6-dichlorophenyl)-5-ethoxy-7-fluoro[1,2,4]triazolo-[1,5-c]pyrimidine-2-sulfonamide ...	84%
Inert Ingredients	16%
Total.....	100%

Contains 0.84 pounds of active ingredient per pound of product.

U.S. Patent No. 5,163,995

Keep Out of Reach of Children

CAUTION
PRECAUCION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

Refer to back panel of bag for additional precautionary information including Personal Protective Equipment (PPE) and User Safety Recommendations.

Agricultural Use Requirements
Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. Refer to label booklet under "Agricultural Use Requirements" in the Directions for Use section for information about this standard

Notice: Read the entire label. Use only according to label directions. **Before buying or using this product, read "Warranty Disclaimer" and "Limitation of Remedies" inside label booklet.**

In case of emergency endangering health or the environment involving this product call 1-800-992-5994. If you wish to obtain additional product information, visit our web site at www.dowagro.com.

Agricultural Chemical: Do not ship or store with food, feeds, drugs or clothing.

EPA Reg. No. 62719-288

EPA Est. 46275-IL-2
900-006954 / 00128019

*Trademark of Dow AgroSciences LLC
Dow AgroSciences LLC
Indianapolis, IN 46268 U.S.A.

Herbicide Net Wt [5 x (2 x 0.45 oz)] water soluble packets

PEEL FILM HERE ➤

Precautionary Statements

Hazards to Humans and Domestic Animals

CAUTION

Causes Moderate Eye Irritation • Harmful If Absorbed Through Skin

Avoid contact with eyes, skin, or clothing.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

First Aid

If in eyes: Flush with plenty of water. Get medical attention if irritation persists.
If on skin: Wash with plenty of soap and water. Get medical attention if irritation persists.

Environmental Hazards

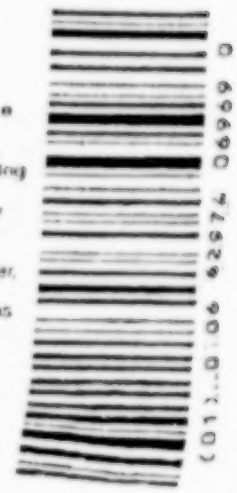
Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or when disposing of equipment washwaters.

This chemical and its transformation products demonstrate the properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.

This chemical can contaminate surface water through spray drift.

Under some conditions, this chemical, and/or its transformation products, may have a high potential for runoff into surface water (primarily via dissolution in runoff water), for several weeks post-application. Vulnerable conditions include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water.

Refer to inside of label booklet for Directions for Use including Storage and Disposal.



(01)...0 06 62 74 06 96 9 0

Dow AgroSciences™

Strongarm®

For Broadleaf Weed Control in Peanuts

Refer to inside of label booklet for additional precautionary information including Personal Protective Equipment (PPE), User Safety Recommendations, and Directions for Use including Storage and Disposal.

EPA Reg. No. 62719-288

EPA Est. 46275-IL-2
900-006953 / 00129103

*Trademark of Dow AgroSciences LLC
Dow AgroSciences LLC • Indianapolis, IN 46268 U.S.A.

Herbicide

NOTES

Active Ingredients:	
diclosulam: N-(2,6-dichlorophenyl)-5-ethoxy-7-fluoro[1,2,4]triazolo-[1,5-c]pyrimidine-2-sulfonamide	84%
Inert Ingredients	16%
Total	100%

Contains 0.84 pounds of active ingredient per pound of product.

U.S. Patent No. 5,163,995

Precautionary Statements

Hazards to Humans and Domestic Animals

CAUTION PRECAUCION

Si usted no entiende la etiqueta, busque á alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

Causes Moderate Eye Irritation • Harmful If Absorbed Through Skin

Avoid contact with eyes, skin, or clothing.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

First Aid

If in eyes: Flush with plenty of water. Get medical attention if irritation persists.
If on skin: Wash with plenty of soap and water. Get medical attention if irritation persists.

Environmental Hazards

Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or when disposing of equipment washwaters.

This chemical and its transformation products demonstrate the properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.

This chemical can contaminate surface water through spray drift.

Under some conditions, this chemical, and/or its transformation products, may have a high potential for runoff into surface water (primarily via dissolution in runoff water), for several weeks post-application. Vulnerable conditions include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water.

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Read all Directions for Use carefully before applying.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your state or tribe, consult the agency responsible for pesticide regulation.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours. **Exception:** If the product is soil-injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls
- Waterproof gloves
- Shoes plus socks

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Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.
Storage: Store in original container only. In case of leak or spill, contain material with absorbent materials and dispose as waste.
Disposal: Wastes resulting from the use of this product may be disposed of on site according to label use directions or at an approved waste disposal facility.
Container Disposal: When all packets are used, dispose of empty package in a sanitary landfill or by incineration or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

General Information

Strongarm* herbicide is a soil-applied product for control of broadleaf weeds in peanuts.

Soil application: A single preplant incorporated, preplant surface, or preemergence application may be made in peanuts.

General Use Precautions and Restrictions

Maximum Application Rates

- In peanuts, do not apply more than 0.45 oz of Strongarm per acre per year in any combination of preplant incorporated, preplant surface, or preemergence applications.
- **Note:** Only a single soil application per growing season may be made in peanuts.

Preharvest Interval: Do not harvest peanuts for 30 days following application.

Read and carefully follow all applicable directions, precautions and restrictions on labeling for other products used in combination with Strongarm.

Aerial application of this product is prohibited.

Do not allow livestock to graze treated areas or harvest forage or hay from treated areas.

Iron Chlorosis: There are isolated areas of the country where soil-induced iron chlorosis routinely occurs. Severity of iron chlorosis symptoms may increase when Strongarm is soil-applied in areas with a history of soil-induced iron chlorosis or other nutrient induced crop injury.

Proper Handling Instructions

This product may not be mixed or loaded within 50 feet of any wells (including abandoned wells and drainage wells), sink holes, perennial or intermittent streams and rivers, and natural or impounded lakes and reservoirs. This setback does not apply to properly capped or plugged abandoned wells and does not apply to impervious pad or properly diked mixing/loading areas.

Operations that involve mixing, loading, rinsing, or washing of this product into or from pesticide handling or application equipment or containers within 50 feet of any well are prohibited unless conducted on an impervious pad constructed to withstand the weight of the heaviest load that may be positioned on or moved across the

pad. Such a pad shall be designed and maintained to contain any product spills or equipment leaks, container or equipment rinse or washwater, and rainwater that may fall on the pad. Surface water shall not be allowed to either flow over or from the pad, which means the pad must be self contained. The pad shall be sloped to facilitate material removal. An unroofed pad shall be of sufficient capacity to contain at a minimum 110% of the capacity of the largest pesticide container or application equipment on the pad. A pad that is covered by a roof of sufficient size to completely exclude precipitation from contact with the pad shall have a minimum containment capacity of 100% of the capacity of the largest pesticide container or application equipment on the pad. Containment capacities as described above shall be maintained at all times. The above specific minimum containment capacities do not apply to vehicles when delivering pesticide shipments to the mixing/loading site. States may have in effect additional requirements regarding wellhead setbacks and operational containment.

Chemigation: Do not apply this product through any type of irrigation system.

Do not use flood irrigation to apply or incorporate this product.

This product must be used in a manner that will prevent back siphoning in wells, spills or improper disposal of excess pesticide, spray mixtures or rinsates.

Crop Rotation Interval for Common Crops

Crop	Rotation Interval (1) (Months)
soybeans, peanuts	no restriction
wheat, barley	4
oats, rye	6
cotton	10
corn (2), rice, tobacco, sorghum	18
sugar beets, sunflowers and other crop not listed	30 (3)

1. Minimum number of months that must pass before planting other crops after application of Strongarm at up to 0.45 oz/acre in peanuts.
2. The crop rotation interval for corn hybrids identified as "IR" is 10 months.
3. Rotation to sugar beets, sunflowers, and all other crops not listed requires a 30-month rotation interval and a successful field bioassay.

Field Bioassay Instructions

Using typical tillage, seeding practices, and timings for the particular crop, plant several strips of the desired crop variety across the field previously treated with Strongarm. Plant the strips perpendicular to the direction Strongarm was applied. The strips should also be located so that different field conditions are encountered, including differences in soil texture, pH, and drainage. If the crop does not show visible symptoms of injury, stand reduction, or yield reduction, the field can be seeded with the test crop in the growing season following the bioassay. If visible injury, stand reduction, or yield reduction occurs, the test crop should not be seeded, and the bioassay must be repeated the next growing season.

Mixing and Appiication

Spray Volume and Application

Apply Strongarm in sufficient spray volume to provide uniform coverage. A spray volume of 10 or more gallons per acre is recommended for soil applications. Sufficient agitation should be maintained during mixing and spraying to ensure a uniform spray mixture. Apply with ground equipment using standard low pressure (20 to 40 psi) herbicide sprayers equipped with nozzles that provide uniform spray coverage. Screens in spray lines should be no finer than 50 mesh (100 mesh is finer than 50 mesh)..

Strongarm Applied Alone

Strongarm water dispersible granules are provided in water soluble packets that require thorough mixing. **Note:** The water soluble packets are not soluble in liquid fertilizer. If applied in liquid fertilizer, Strongarm must be pre-mixed (slurried) with water and then added to the liquid fertilizer solution. Premixing may also be used to aid in mixing with water. See pre-mixing instructions below.

Handling Precautions for Water Soluble Packets: Do not remove water soluble packet from overpack except for immediate use. Do not open water soluble packets (product in transparent film). Do not allow water soluble packet to come into contact with water prior to use. Do not handle water soluble packet with wet hands or wet gloves. Carefully reseal overpack containing unused water soluble packets and protect package from moisture.

Determining the Number of Water Soluble Packets Required:

Application Rate (oz/acre)	Acres per Individual Bubble Packet
0.45 †	1.0

Formula: Acres to be treated ÷ Acres/Packet = Number of Packets

Mixing Order:

1. Fill the tank with ½ of the total amount of water or liquid fertilizer for the load. **Note:** If liquid fertilizer is being used as the spray carrier, water-soluble packets must be pre-mixed as described below before adding to the spray tank. Start the agitation system.
2. Add water soluble packets by opening the overpack and adding the packet (product in transparent film) directly into the spray tank while agitating. Before spraying, make sure packets have completely disintegrated and product is thoroughly mixed with water. Depending on the water temperature and the degree of agitation, the packet and its contents should be completely dispersed within 5 minutes from the time they were added to the water.
3. Continue agitation and finish filling tank.

Note: To ensure a uniform spray mixture continuous agitation is required during application. If product is allowed to settle, thoroughly agitate to resuspend the mixture before spraying. To ensure product effectiveness, apply within 24 hours of mixing. Weed control with Strongarm that has been mixed and allowed to stand for more than 48 hours may be reduced.

Strongarm Applied in Tank-mix Combination

If a broader spectrum of weed control is required, Strongarm may be tank-mixed with labeled rates of other herbicides provided: (1) the tank mix product is labeled for the timing and method of application for the use site to be treated; and (2) tank mixing is not prohibited by the label of the tank mix product.

Tank Mixing Precautions:

- Read carefully and follow all applicable use directions, precautions, and limitations on the respective product labels.
- Do not exceed recommended application rates for respective products or maximum allowable application rates for any active ingredient in the tank mix.
- For products packaged in water soluble packaging, do not tank mix with products containing boron or mix in equipment previously used to apply a product mixture containing boron unless the tank and spray equipment has been adequately cleaned. (See Equipment Clean-Out Procedures.)
- Always perform a (jar) test to ensure the compatibility of products to be used in tank mixture.

Tank Mix Compatibility Testing: A jar test is recommended prior to tank mixing to ensure compatibility of Strongarm and other pesticides. Use a clear glass quart jar with lid and mix the tank mix ingredients in their relative proportions. Invert the jar containing the mixture several times and observe the mixture for approximately ½ hour. If the mixture balls-up, forms flakes, sludges, jels, oily films or layers, or other precipitates, it is not compatible and the tank mix combination should not be used.

Vigorous, continuous agitation during mixing, filling and throughout application is required for all tank-mixes. Sparger type agitators generally provide the most effective agitation in spray tanks. To prevent foaming in the spray tank, avoid stirring or splashing into the spray mixture.

Mixing Order for Tank-mixes:

1. Fill the spray tank to ½ of the total spray volume required with water or liquid fertilizer. **Note:** If liquid fertilizer is being used as the spray carrier, water-soluble packets must be pre-mixed as described below before adding to the spray tank. Start the agitation system.
2. Add water soluble packets by opening the overpack and adding water soluble packet (product in transparent film) directly into the spray tank while agitating and allow time to disperse. Allow time for complete mixing (approximately 5 minutes). Before adding other products, make sure packets have completely disintegrated and product is thoroughly mixed.
3. Add different formulation types in the following order: (1) Other formulation packaged in water soluble film; (2) Any compatibility agent, if required; (3) other dry flowables; (4) wettable powders; (5) aqueous suspensions, flowables and liquids. Maintain agitation and fill spray tank to ¾ of total spray volume and add: (5) emulsifiable concentrates and (6) solutions (i.e., fertilizers). Allow time for complete mixing after each addition.
4. Finish filling the spray tank. Maintain continuous agitation during mixing and throughout application.

If application or agitation must be stopped before the spray tank is empty, the materials may settle to the bottom. Settled materials must be re-suspended before spraying is resumed. A sparger agitator is particularly useful for this purpose. Settled material may be more difficult to re-suspend than when originally mixed.

Pre-mixing (Slurry) of Water Soluble Packets

The film used in water soluble packaging for Strongarm is not soluble in liquid fertilizer solutions. In order to add Strongarm to liquid fertilizer carrier, the product must be premixed with water. Pre-mixing is also an alternative mixing method for application in water. Use a minimum 2 fl oz of water for each individual 0.45 oz water soluble packet of Strongarm. The packets can be stirred immediately on addition to water or allowed to dissolve. Stir (or shake if pre-mixed in a closed container) until the packets are completely dissolved and granules are dispersed and then add to the spray tank or inductor (recommended through a 20-35 mesh screen). Rinse container used for pre-mixing and add rinsate to spray tank.

Pre-mixing (other products): If pre-mixing is required for other dry or flowable products applied in tank-mix combination with Strongarm, follow recommendations for pre-mixing of such products provided in their respective product labels.

Equipment Clean-out Procedures:

1. Drain any remaining spray mixture from the application system.
2. Hose down the interior surfaces of the tank while filling the tank ½ full with water.

3. Add household ammonia, at a rate of 1 gallon per 100 gallons of water. Recirculate for 5 minutes and spray out part of this mixture for 5 minutes through the boom. Drain tank.
4. Remove all spray nozzles and screens and clean separately.

Note: If this spray equipment will be used on a crop that is sensitive to Strongarm, steps 1-3 should be repeated. Exterior surfaces of spray equipment should also be washed thoroughly.

All rinsate should be disposed of on site or at an approved waste disposal facility.

Approved Uses

PEANUTS (Soil Application)

Strongarm may be used in various tillage programs including, but not limited to, strip till, no till and conventional tillage operations. Application of Strongarm on soils with greater than 5% organic matter may result in reduced weed control and require subsequent postemergence applications of other herbicides appropriate for specific weeds. Do not use on peat or muck soils. Season-long control of severe weed infestations may require a postemergence application of complimentary herbicides following application of Strongarm.

Note: Environmental and soil factors can influence the performance and selectivity of any herbicide treatment. Rainfall of 0.5 inches or greater is required for optimum weed control by most soil herbicides, including Strongarm. Strongarm and other herbicides when incorporated will perform most optimally when evenly distributed in the surface soil. When emergence of the planted crop is delayed due to unusually cool and/or wet conditions, factors such as pH, disease, and nutrient deficiencies can contribute to reduced crop tolerance to a soil-applied herbicide.

Cultivation: If required, cultivation should be shallow to avoid excessive movement of treated soil and to avoid exposing weed seed buried deep within the soil.

Area of Use (Peanuts): Use of Strongarm is recommended in all areas where peanuts are grown.

Application Rates	
Crop	Strongarm (oz/acre)
Peanuts	0.45
Weeds Controlled	
bristly starbur common cocklebur common lambsquarters common ragweed common sunflower eclipta	devil's-claw Florida beggarweed giant ragweed morningglory species nutsedge species (1, 2) Palmer amaranth	Pennsylvania smartweed prickly sida redroot pigweed smooth pigweed spurred anoda	spurge species shining tickweed tropic croton Virginia Copper Leaf velvetleaf wild poinsetta

Note: Numbers in parentheses "(-)" refer to footnotes below.

1. Heavy infestations may require postemergence application of complimentary herbicides following a soil application of Strongarm for season-long control.

2. The level of nutsedge control provided by Strongarm on nutsedge can vary depending on weed density and soil or environmental conditions.

   For best results:
   - Fields should be clean-tilled and weed-free.
   - Apply Strongarm as close as possible to planting.
   - If irrigation is available, immediately apply 0.25 to 0.5 inch of water.
   - Cultivation, a tank mixture, or applications of postemergence herbicides may also be needed to achieve desired level of control.

Application Directions

Preplant Incorporated Application

Apply Strongarm alone or in tank-mix combination with other herbicides registered for preplant incorporated application. Apply to a seedbed that is relatively free of clods. Incorporate the herbicide(s) into the top 1 to 3 inches of the final seedbed using equipment that provides thorough soil mixing. Do not apply Strongarm more than 4 weeks before planting. For optimum results, apply Strongarm at or just prior to planting. When Strongarm is applied in tank-mix combination with other herbicide(s), follow the incorporation directions for the tank-mix partner(s). Follow applicable use instructions, including application rates, precautions and restrictions or each product used in the tank-mixture.

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Preplant Surface Application

Apply Strongarm alone or in tank-mix combination with other herbicides registered for preplant soil surface applications. Apply to a seedbed that is relatively free of clods. Do not apply Strongarm more than 4 weeks before planting. For optimum results, apply Strongarm at or just prior to planting. Soil surface applications are not effective until rainfall or irrigation of at least 0.25 - 0.5 inches has moved Strongarm into soil where weed germination occurs. If rainfall is not anticipated, shallow (i.e., 2 inches) incorporation prior to planting is recommended to place Strongarm in contact with germinating weeds. If applied in tank-mix combination, follow use instructions, including application rates, precautions and restrictions of each product used in the tank-mixture. For minimum-tillage or no tillage or reduced tillage systems, when weeds are present at the time of application, apply in a tank mix combination a contact herbicide such as Starfire or Roundup herbicide.

Note: Reduced weed control in the planted row may occur from exposure of untreated soil during the planting operation if surface applications are not incorporated prior to planting.

Preemergence Application

Apply after planting but prior to crop or weed emergence. Preemergence applications are not effective until rainfall or irrigation of at least 0.25 - 0.5 inches has moved Strongarm into the soil where weed germination occurs. Strongarm may be applied alone or in tank-mix combination with herbicides registered for preemergence application. When applied in tank-mix combination, follow applicable use instructions,

including application rates, precautions and restrictions of each product used in the tank-mixture. For optimum results, Strongarm should be applied at or near planting, prior to germination of weeds and emergence of the crop.

Minimum Tillage, No Tillage, Strip Tillage, or other reduced tillage systems

In these tillage systems, where peanuts are planted directly into a cover crop, stale seedbed, or previous crop residues, a contact herbicide such as Starfire or Roundup may be tank mixed with Strongarm to control existing weeds. Apply before, during (behind the planter), or after planting, but before the crop emerges.

Strongarm Followed by Postemergence Treatments

Weeds and grasses not controlled by Strongarm may be controlled with postemergence herbicide products. Follow the postemergence manufacturer's labels for application rates, weeds controlled, applicable use directions, precautions and limitations before use.

Warranty Disclaimer

Dow AgroSciences warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in strict accordance with the directions, subject to the inherent risks set forth below. Dow AgroSciences MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

Inherent Risks of Use

It is impossible to eliminate all risks associated with use of this product. Crop injury, lack of performance, or other unintended consequences may result because of such factors as use of the product contrary to the label instructions (including adverse conditions noted on the label, such as unfavorable temperatures, soil conditions, etc.), abnormal conditions (such as excessive rainfall, drought, tornadoes, hurricanes), presence of other materials, the manner of application, or other factors, all of which are beyond the control of Dow AgroSciences or the seller. All such risks shall be assumed by the buyer.

Limitation of Remedies

The exclusive remedy for losses or damages resulting from the use of this product (including claims based on contract, negligence, strict liability, or other legal theories), shall be limited to, at Dow AgroSciences' election, one of the following:

1. Refund of purchase price paid by buyer or user for product bought, or
2. Replacement of amount of product used.

Dow AgroSciences shall not be liable for losses or damages resulting from handling or use of this product unless Dow AgroSciences is promptly notified of such loss or damage in writing. In no case shall Dow AgroSciences be liable for consequential or incidental damages or losses.

The terms of the Warranty Disclaimer above and this Limitation of Remedies cannot be varied by any written or verbal statements or agreements. No employee or sales agent of Dow AgroSciences or the seller is authorized to vary or exceed the terms of the Warranty Disclaimer or this Limitation of Remedies in any manner.

*Trademark of Dow AgroSciences LLC

NOTES

Supplemental Labeling

Dow AgroSciences

Dow AgroSciences LLC 9330 Zionsville Road Indianapolis, IN 46268-1054 USA

Strongarm*

EPA Reg. No. 62719-288

Preemergence Broadleaf Weed Control in Peanuts

(For Distribution and Use Only in the states of New Mexico, Oklahoma and Texas)

ATTENTION

- It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
- This labeling must be in the possession of the user at the time of application.
- Read the label affixed to the container for Strongarm before applying. Carefully follow all precautionary statements and applicable use directions.
- Except as described in this supplemental labeling, use of Strongarm is subject to all precautions and limitations imposed by the labels affixed to the containers for Strongarm.

Directions for Use

Strongarm* herbicide may be soil-applied as a broadcast or band application for preemergence control of broadleaf weeds in peanuts. Strongarm may be applied alone or in tank mix combination with other herbicides registered for preemergence use in peanuts.

Mixing and Application: Follow mixing directions in the label booklet attached to the product container. Apply Strongarm in sufficient spray volume to provide uniform coverage. A spray volume of 10 or more gallons per acre is recommended for soil applications.

For band applications, use nozzles designed for even application within the band (usually with an "E" designation). If you are unsure about the suitability of a particular nozzle for band application, consult the manufacturer's specifications. The following formula may be used to determine the amount of herbicide needed.

$$\frac{\text{Band width in inches}}{\text{Row width in inches}} \times \text{Broadcast rate per acre} = \text{Amount needed per acre of field}$$

Determining the Number of Water Soluble Packets Required:

Application Rate (oz/acre)	Acres per Individual Bubble Packet
0.3 - 0.45	1.5 to 1.0

Formula: Acres to be treated ÷ Acres/Packet = Number of Packets

Sample Calculation: Acres to be treated = 31
Rate Needed = 0.3 oz/A
Acres/Packet = 1.5 acres/packet
31 acres ÷ 1.5 acres per packet = 20.66 packets
(20.66 packets rounded up to nearest whole number of packets = 21 packets)

Preemergence Application

Texas and New Mexico: Apply Strongarm at the rate of 0.45 oz as a preemergence application from no less than 5 days after planting through "at-cracking†".

Oklahoma: Strongarm, preemergence at the rate of 0.3 oz per acre may be applied from immediately after planting through "at-cracking". Strongarm at the 0.45 oz per acre rate may be applied from no less than 5 days after planting through "at-cracking".

† **"Cracking"** of soil occurs when soil is displaced by germinating seedlings just prior to emergence.

Peanuts should be planted at least 1 1/2 inches deep. For best results, soil moisture should be sufficient for immediate germination. When Strongarm is soil applied, rainfall or irrigation equal to 0.25 to 0.5 inches is required for herbicidal activation and to move the active ingredient into the zone of weed germination. Under dry soil conditions, a minimum of 0.5 inches of rain/irrigation water is necessary for herbicidal activation. If weeds have emerged prior to application, use an appropriate contact herbicide to control the weeds that are present.

Application Rates	
Crop	**Strongarm (oz/acre)**
Peanuts	0.3 - 0.45
Weeds Controlled	
bristly starbur	Pennsylvania smartweed
common cocklebur	prickly sida
common lambsquarters	redroot pigweed
common ragweed	smooth pigweed
common sunflower	spurge species
eclipta (1)	spurred anoda
devil's-claw	shining tickweed
Florida beggarweed	tropic croton
giant ragweed	velvetleaf
morningglory species (1)	Virginia copperleaf (1)
nutsedge species (1, 2, 3)	wild poinsetta
Palmer amaranth	

Note: Numbers in parentheses "(-)" refer to footnotes below.

1. When using the 0.3-oz rate, weed control results on eclipta, morningglory, nutsedge, and Virginia copperleaf may be variable. A follow up treatment with another herbicide may be necessary for full season control.
2. Heavy infestations may require postemergence application of complimentary herbicides following a soil application of Strongarm for season-long control.
3. The level of nutsedge control provided by Strongarm can vary depending on weed density and soil or environmental conditions (especially moisture).

For best weed control results:

- Fields should be clean-tilled and weed-free.
- Cultivation, a tank mixture, or applications of postemergence herbicides may also be needed to achieve desired level of weed control.

Tank Mixing: Strongarm may be applied in tank mix combination with labeled rates of other herbicides labeled for preemergence application to peanuts provided: (1) the tank mix product is labeled for the timing and method of application for the use site to be treated; and (2) tank mixing is not prohibited by the label of the tank mix product. When applied in tank mix combination with other herbicides, follow applicable use instructions, including application rates, precautions and restrictions for each product used in the tank mixture, including use of adjuvants. Refer to the product label booklet for Strongarm for detailed information on tank mixing.

Minimum CT

Minimum Tillage, No Tillage, Strip Tillage, or other reduced tillage systems: In these tillage systems, where peanuts are planted directly into a cover crop, stale seedbed, or previous crop residues, a burndown application of a herbicide such as Gramoxone Max, or glyphosate-containing product† such as Roundup UltraMAX, Glyphomax, or Glyphomax Plus should be used to control existing weeds. Do not rely on Strongarm for post emergence control of emerged weeds.

† When tank mixing with glyphosate and ammonium sulfate, add ammonium sulfate to the tank mixture before adding glyphosate.

Strongarm Followed by Postemergence Treatments: Weeds and grasses not controlled by Strongarm may be controlled with postemergence herbicide products. Follow the manufacturer's label for the postemergence product for application rates, weeds controlled, applicable use directions, precautions and limitations before use.

Use Precautions and Restrictions:

- **Preharvest Interval:** Do not harvest peanuts for 30 days following application.
- Maximum Use Rate for Peanuts: Do not apply more than 0.45 oz of Strongarm per acre per year.
- Do not apply Strongarm to soils with a pH of 7.2 or greater.
- Seeds that have low germination or low early season vigor have shown more susceptibility to environmental stress and herbicide injury. Do not apply Strongarm to peanut varieties with a warm germination test of less than 80% germinable seed.
- Seeds must be planted at least 1 1/2 inches deep.
- Extended cold wet conditions, following applications of Strongarm, which persist during germination and early crop development will result in crop injury. Do not apply Strongarm when below normal soil and/or air temperatures are expected within 5 days of application.
- **Aerial application of this product is prohibited.**
- **Chemigation:** Do not apply this product through any type of irrigation system.
- Rainfall or irrigation immediately following application may increase potential for crop injury especially under persistent cool conditions.
- Preemergence applications are not effective until rainfall or irrigation of at least 0.25 – 0.5 inches has moved Strongarm into the soil where weed germination occurs. Under dry soil conditions, a minimum of 0.5 inches of rain/irrigation water is necessary for herbicidal activation.
- Do not use Strongarm in peanuts grown under drip irrigation. Peanuts grown under drip irrigation must rely on timely rainfall to uniformly moisten the soil since pegging will not occur where surface soil is dry.
- Do not use flood irrigation to apply or incorporate Strongarm.
- When using furrow irrigation, weed control results will be variable if no rainfall is received within 2 weeks of application of Strongarm.
- Avoid use of irrigation water that does not meet irrigation water quality standards published by state or land grant universities. If no standards have been published, use guidelines in the Western Fertilizer Handbook. Poor water quality can injure or kill peanuts.
- Do not allow livestock to graze treated areas or harvest forage or hay from treated areas.

*Trademark of Dow AgroSciences LLC

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action
	)	No. 5-01CV0331-C
DENNIS BATES, [*et al.*],	)	
	)	
Defendants.	)	

[Filed Apr. 10, 2002]

DEFENDANTS' FIRST AMENDED COUNTERCLAIM

TO THE HONORABLE JUDGE OF SAID COURT:

NOW COME COUNTER-PLAINTIFFS, DENNIS BATES, JIMMY BURSON BENNY JUDAH d/b/a CLEARWATER FARMS, RICHARD COX, WAYNE DAVIS, TODD DENMAN, Personal Representative of the Estate of BURK DENMAN, NEIL FRIESEN, JAKE FROESE, THOMAS R. FUSTON, ARTHUR GALVAN d/b/a G-5 PARTNERSHIP, GREG HUGHES, GREG HUGHES and KARL DON HUGHES d/b/a JH CATTLE COMPANY, RUDY KLASSEN, RONNIE N. LOVE, KEVIN MATHIS, BRAD PALMER, KIRK PARRISH d/b/a K-L FARMS, JERRY PARRISH, JOEVELYN PATTERSON and DONALD C. GRUBEN, STACY LEE PRICE, BENNY JUDAH d/b/a PROGRESSIVE FARMS, MORRIS RUSHING d/b/a PEA-COT FARMS, BILLY SHANNON, CRAIG WEST and FRENCHIE LEE WHEELER complaining of DOW AGROSCIENCES LLC, hereinafter referred to as Counter-Defendant, and for

cause of action would respectfully show unto the Court as follows:

I.

Counter-Plaintiffs are each defendants named in Plaintiff's Complaint for Declaratory Relief filed in this Court.

Counter-Defendant DOW AGROSCIENCES LLC is a foreign corporation or joint-stock association doing business in the state of Texas. Dow AgroSciences LLC is before the Court and no service of process is necessary upon the Counter-Defendant.

II.

FACTS

Counter-Plaintiffs are farmers who now own or in the past have owned and operated lands and peanut farms. This action arises out of damages suffered by Counter-Plaintiffs as a result of the use of Strongarm®, a herbicide designed, formulated, developed, produced and manufactured by Counter-Defendant Dow AgroSciences LLC and sold and distributed through the stream of commerce by Dow AgroSciences LLC's retail distributors. At all relevant times, the Strongarm®, before it left Dow AgroSciences LLC, had been rendered ineffective as a herbicide. The peanuts treated with Strongarm® did not grow properly, were stunted, did not properly develop foliage and delayed in maturing for harvest resulting in increase expense and production in reduced profit from sale and harvest. On information and belief, Counter-Plaintiffs used the Strongarm® on the peanut farms in the year 2000 which did irreparable damages to Counter-Plaintiffs' harvests and the lands in the years 2000 and 2001.

III.

NEGLIGENCE

The Counter-Defendant Dow AgroSciences LLC was negligent in the development, testing, manufacture, production and promotion of Strongarm®. The injuries and damages to the Counter-Plaintiffs peanut crops for the years 2000 and 2001 were directly and proximately caused by the negligence and carelessness of Counter-Defendant.

Further, the attempted disclaimer of warranties and limitations of remedies are not conspicuous, did not comply with state or federal law and are therefore ineffective and void.

IV.

DECEPTIVE TRADE PRACTICE ACT

At all relevant times to this suit, Counter-Plaintiffs were acting as "consumers" as defined in the Tex. Bus. & Comm. Code Ann. §17.45(4) (Vernon's 1987) of the Deceptive Trade Practices Act ("DTPA") and were engaged in "trade and commerce" as defined in the Act.

This suit is brought against Counter-Defendant pursuant to the provisions of §17.41 *et. seq.* of the DTPA because, in violation of certain provisions of the DTPA, the Counter-Defendant:

(a) represented that Strongarm® had sponsorship, approval, characteristics, uses or benefits which it did not have; and,

(b) represented that Strongarm® was of a particular standard, quality, or grade, when in fact, it was another.

Each and every one of the foregoing acts and omissions, taken separately and collectively, constitutes a

producing cause of the damages sustained by each Counter-Plaintiff, as more particularly set forth below.

Counter-Defendant knew or had reason to know that its product, Strongarm®, would be used by peanut farmers. In this connection, Counter-Defendant knew or had reason to know of such particular purpose because its product, Strongarm®, was designed, manufactured, sold and intended for use as a herbicide, and Counter-Defendant advertised and touted the supposedly outstanding characteristics of Strongarm® for such purposes. As a result, Counter-Defendant knew or had reason to know that each Counter-Plaintiff was relying on Counter-Defendant's skills and judgment to supply a product suitable for its intended use. Each Counter-Plaintiff relied on Counter-Defendant's skill and judgment that the product was fit for the particular purposes for which it was to be put. The Strongarm® was, in fact, not suitable for this particular purpose.

Each Counter-Plaintiff would further show that Counter-Defendant has undertaken an unconscionable course of conduct, as that term is defined by §17.45(5) of the DTPA. Counter-Defendant knew or should have known that Strongarm® was not suitable and would fail, was not of good workmanlike quality, and would eventually cause damage to consumers, including each Counter-Plaintiff. Counter-Defendant's conduct was an unconscionable course of action, as that term is defined in the Act, in that it resulted in a gross disparity between the value each Counter-Plaintiff gave in consideration for the Strongarm® and the value of the product actually received. Further, said unconscionable course of action took advantage of the lack of knowledge, ability, experience or capacity of each Counter-Plaintiff to know of the substantial latent defects in Strongarm® and, as such, took advantage of each Counter-Plaintiff's lack of knowledge, experience and capacity to a grossly unfair

degree. Said unconscionable course of action was a producing cause of damages to each Counter-Plaintiff.

Counter-Defendant committed the above-described violations of the DTPA knowingly, as that term is defined in the Act. The unconscionable action or course of action by Counter-Defendant was done knowingly and with actual awareness of the unfairness of such acts or practices. Each Counter-Plaintiff requests an award of two times the amount of actual damages under $1,000.00 and three times each Counter-Plaintiff's actual damages over $1,000.00, pursuant to §17.50 of the DTPA.

Each Counter-Plaintiff would further show that recovery of court costs and attorney's fees are authorized under the Act.

Further, the attempted disclaimer of warranties and limitations of remedies are not conspicuous, did not comply with state or federal law and are therefore ineffective and void.

V.

BREACH OF CONTRACT

It was in the contemplation of the parties when the contract for purchase of Strongarm® that is the basis of this suit was signed that the Counter-Plaintiffs would use the Strongarm® on the peanut crop to engage in the business of peanut farming with the expectation of generating substantial income with a reasonable net profit. The Strongarm®'s failure to perform has totally destroyed all the Counter-Plaintiffs' prospects to profit from the intended activity. Further, each Counter-Plaintiff has incurred additional expense in growing the crop to harvest. Each Counter-Plaintiff has suffered loss of the benefit of the bargain, consequential damages and incidental expenses.

Further, the attempted disclaimer of warranties and limitations of remedies are not conspicuous, did not

comply with state or federal law and are therefore ineffective and void.

VI.

BREACH OF EXPRESS AND IMPLIED WARRANTIES

Prior to the purchase of the Strongarm® by each Counter-Plaintiff, Counter-Defendant induced purchases of the Strongarm® by expressly warranting to each Counter-Plaintiff by advertisements directed to the attention of the public, and particularly to the ultimate consumers, that such consumers, including each Counter-Plaintiff, could safely use Strongarm® in treating their peanut crop and that it would not damage or harm the land or peanut crop growing thereon. The Counter-Defendant expressly warranted Strongarm® as being reasonably fit for the purposes stated and as a product that was effective in treating many types of agricultural crops or plants for weeds without limitations.

In purchasing the Strongarm®, each Counter-Plaintiff relied on the reputation, skill and judgment of the Counter-Defendant and upon Counter-Defendant's express warranties, as described above.

At the time of the purchase of the Strongarm® by each Counter-Plaintiff, the express warranties about the efficacy of Strongarm® was not true and the Strongarm® was not reasonably suitable and fit for use, and as a direct result of said breach of express warranties, the injury and damages occurred, as set forth herein.

As a direct and proximate result of the breach of express warranties by the Counter-Defendant, each Counter-Plaintiff sustained substantial damages to his lands and peanut crops continuing to the present time, and expects to incur substantial future damage to the land and peanut crops caused by the Counter-Defendant's product.

In addition, Counter-Defendant impliedly warranted that Strongarm® was merchantable and was fit for the purpose for which it was manufactured, that it was a safe and suitable herbicide to be used in peanut crops for weeds.

Strongarm® was, in fact, not fit for its intended purpose as warranted by Counter-Defendant and as a proximate result of the breach of warranty of fitness, each Counter-Plaintiff sustained injuries and damages as alleged below.

Further, the attempted disclaimer of warranties and limitations of remedies are not conspicuous, did not comply with state or federal law and are therefore ineffective and void.

VII.

STRICT LIABLITY IN TORT

The Strongarm® purchased by each Counter-Plaintiff was designed, formulated, developed, produced, manufactured and sold by Counter-Defendant. At all relevant times, the Strongarm® before it left Dow AgroSciences, LLC was defective, which defect rendered the product unreasonably dangerous as a herbicide and the Counter-Defendant is liable and damages to each Counter-Plaintiff under the provisions of §402a and §402b, Restatement of Torts 2d. The defective nature of the Strongarm® was a producing cause of damages to each Counter-Plaintiff.

Further, the attempted disclaimer of warranties and limitations of remedies are not conspicuous, did not comply with state or federal law and are therefore ineffective and void.

VIII.

FRAUD AND FRAUD IN THE INDUCEMENT

Dow AgroSciences, LLC and its local retail distributors who sold the product to each Counter-Plaintiff represented that the Strongarm® was an excellent herbicide for use in peanuts. Based on this representation, each Counter-Plaintiff purchased and used Strongarm® as instructed. Shortly after using the Strongarm® each Counter-Plaintiff noticed that the peanuts were not growing and maturing and called this fact to Dow AgroSciences LLC and their representatives' attention. Dow AgroSciences LLC acting by and through its agents and representatives represented to each Counter-Plaintiff that if they would grow the peanut crop to maturity the delay in growth and stunting would resolve itself and it would make a normal crop and, if it did not, Dow AgroSciences LLC would pay each Counter-Plaintiff for his loss of profit and all other losses and damages.

Each Counter-Plaintiff detrimentally relied upon this representation and suffered losses and damages.

Further, the attempted disclaimer of warranties and limitations of remedies are not conspicuous, did not comply with state or federal law and are therefore ineffective and void.

IX.

ESTOPPEL AND WAIVER

Dow AgroSciences LLC and its local retail distributors represented to each Counter-Plaintiff that Strongarm® was an excellent herbicide for use in peanuts. Based on this representation, each Counter-Plaintiff purchased and used Strongarm® as instructed. Shortly after using the Strongarm® each Counter-Plaintiff noticed that the peanuts were not growing and maturing and called this fact to Dow AgroSciences LLC and their

representatives' attention. Dow AgroSciences LLC represented to the Counter-Plaintiffs that if they would grow to maturity the delay in growth and stunting would resolve itself and it would make a normal crop and, if it did not, Dow AgroSciences LLC would pay each Counter-Plaintiff for his loss of profit and for all other losses and damages.

Each Counter-Plaintiff detrimentally relied on this representation and suffered losses and damages. Dow AgroSciences LLC is estopped to rely upon disclaimer of warranties or limitations of remedies as a result of its conduct. Dow AgroSciences LLC has waived its disclaimer of warranties and limitations of remedies provision as a result of its conduct in relation to each Counter-Plaintiff.

Further, the attempted disclaimer of warranties and limitations of remedies are not conspicuous, did not comply with state or federal law and are therefore ineffective and void.

X.

NEGLIGENT REPRESENTATION

The Counter-Defendant, acting by and through its field representatives and authorized retail distributors promoted Strongarm® as an excellent herbicide for use in west Texas peanuts. The Counter-Plaintiff growers each relied on their representations about the many beneficial qualities and characteristics of Strongarm®. The representations were untrue and were made fraudulently and/or negligently. Each of the Counter-Plaintiff growers sustained damage and loss as a result of the justifiable reliance on the misrepresentations concerning Strongarm®.

XI.

DAMAGES (APPLICABLE TO ALL COUNTS)

The acts and omissions of Counter-Defendant were a direct and proximate cause of each Counterplaintiff's

damages, each of which shall continue in the future, including, but not limited to, the following:

(a) loss of profits for the years 2000 and 2001;

(b) reasonable attorney's fees;

(c) all expenses and costs of this litigation;

(d) lawful pre-judgment interest;

(e) lawful post-judgment interest;

(f) additional, statutory and exemplary damages as allowed by common law and allowed by statutory law including the DTPA; and,

(g) any and all other damages of every nature and kind suffered by each Counter-Plaintiff as a consequence of the acts and omissions of the Counter-Defendant as described above.

XII.

All conditions precedent to the filing of this lawsuit and Counter-Plaintiff's remedies have been performed or have occurred.

Each Counter-Plaintiff hereby demands a trial by jury.

XIII.

Each Counter-Plaintiff's claim does not arise under any federal law including 7 U.S.C. §§136-136y, Federal Insecticide, Fungicide and Rodenticide Act and each Counter-Plaintiff does not claim that Strongarm® violated any provision of the Act by its labeling and does not claim any damage to human health or the environment.

WHEREFORE, PREMISES CONSIDERED, each Counter-Plaintiff prays that the Counter-Defendant be cited to appear and answer herein; that at trial, each Counter-Plaintiff have judgment based on the legal remedy providing each Counter-Plaintiff with the greatest

relief against the Counter-Defendant, Dow AgroSciences LLC, for each legal remedy, collectively or in the alternative, for actual damages, additional damages, statutory damages and exemplary damages with interest thereon, both pre-judgment and post-judgment; that actual damages be trebled, and for such other and further additional damages as provided by the DTPA; that each Counter-Plaintiff recover reasonable attorney's fees, expenses of this litigation and costs of court; and for such other and further relief, at law or in equity, to which each Counter-Plaintiff may show himself justly entitled.

Respectfully submitted,

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ATTORNEYS FOR DEFENDANTS/COUNTER-PLAINTIFFS

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action
	)	No. 5-01CV0331-C
DENNIS BATES, [*et al.*],	)	
	)	
Defendants.	)	

[Filed Apr. 15, 2002]

FIRST AMENDED COMPLAINT FOR DECLARATORY RELIEF

Plaintiff Dow AgroSciences LLC ("Dow AgroSciences"), by its attorneys, files this First Amended Complaint for Declaratory Relief and alleges as follows:

JURISDICTION AND VENUE

1. This is a civil action over which this Court has original federal subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (a)(1). There is complete diversity of citizenship between the parties and the matter in controversy exceeds the sum or value of seventy-five thousand ($75,000), exclusive of interest or costs, with respect to each individual Defendant.

2. Venue in this district is proper pursuant to 28 U.S.C. § 1391(a)(1) in that the majority of the defendants reside in this judicial district in the State of Texas and all defendants reside in the State of Texas.

3. Venue in this district is proper pursuant to 28 U.S.C. § 1391(a)(2) because a substantial part of the

events or omissions giving rise to the claims herein occurred in this district and because a substantial part of the property that is the subject matter of this action is situated in this district.

4. This Court also has supplemental jurisdiction over the dispute between Dow AgroSciences and the defendants pursuant to 28 U.S.C. § 1367(a) in that the defendants' claims are part of the same case or controversy as those of the other defendants and arise from the same central core of operative facts.

5. This Court has personal jurisdiction over each defendant pursuant to Tex. Civ. Prac. & Rem. Code Ann. § 17.042.

PARTIES

6. Dow AgroSciences is a Delaware limited liability company with its principal place of business in Marion County, Indiana. Dow AgroSciences LLC was originally created as DowElanco, an Indiana general partnership, on October 31, 1989. DowElanco converted to a limited liability company on July 1, 1997 (DowElanco LLC) and changed its name to Dow AgroSciences effective January 1, 1998. Dow AgroSciences is a citizen of both Delaware and Indiana as provided by 28 U.S.C. § 1332(c)(1).

7. The individual Defendants are a group of individual-peanut crop growers who are citizens of the state of Texas residing in Baylor, Brisco, Brown, Cochran, Collingsworth, Dawson, Eastland, Stephens, Erath, Fisher, Gaines, Hall, Hamilton, Haskell, Lamb, and Yoakum counties ("Defendants"). Defendant Sand Farms, Inc., is a citizen of Texas as provided by 28 U.S.C. § 1332(c)(1).

DECLARATORY JUDGMENT

8. This case involves an actual controversy, within the jurisdiction of this Court, and a judicial declaration is necessary regarding the rights and other legal relations

between the plaintiff Dow AgroSciences and the Defendants, as set out below. Therefore, the relief requested by Dow AgroSciences is specifically authorized by 28 U.S.C. § § 2201 and 2202 and Fed. R. Civ. P. 57.

STATEMENT OF FACTS

9. Dow AgroSciences is, among other things, a manufacturer of pest management and biotechnology products. In the Spring of 2000, Dow AgroSciences introduced a new product, Strongarm*, which was used as a preemergence herbicide to control certain weeds in peanuts. Strongarm was introduced in the Southwest of the United States, including within this district.

10. The active ingredient in Strongarm is diclosulam.

11. Strongarm is registered with the United States Environmental Protection Agency ("EPA") pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y. As part of the initial registration process under FIFRA for the Strongarm herbicide, Dow AgroSciences submitted all scientific data and information required by the EPA. The EPA determined that the data submitted by Dow AgroSciences to the EPA in support of the initial registration of Strongarm herbicide was in compliance with the requirements of FIFRA and registered Strongarm and assigned the registration number 62719-288 on March 8, 2000.

12. As part of the initial registration process for the Strongarm herbicide, Dow AgroSciences received from the EPA a stamped and accepted product label.

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* Trademark of Dow AgroSciences LLC.

13. At all times relevant hereto, Dow AgroSciences has sold the Strongarm herbicide with labels that were accepted by the EPA and affixed to the product at the time of the sale.

14. The growing season in the Southwest in 2000 was challenging. Yields from peanut crops in Texas and Oklahoma were significantly lower than in previous years due to a severe mid-season drought and late-season rain and snow, which made harvest difficult. Water quality and quantity, as well as other cultural management practices, were also questionable.

15. Upon information and belief, near the end of 2000 counsel for various peanut growers were openly soliciting clients for a mass suit against Dow AgroSciences based on the allegation that the lower-than expected yields from peanut crops in Texas and Oklahoma were caused by and attributable solely to the individual growers' use of Strongarm.

16. Seventy-five individual peanut grower's represented by counsel have sent claim demand letters to Dow AgroSciences. Seventy are named as defendants in this action and in an action filed concurrently with this one in the United States District Court for the Western District of Oklahoma, collectively. Each of the individual Defendants' claims exceeds the $75,000 amount in controversy for purposes of jurisdiction pursuant to 28 U.S.C. § 1332 which includes specific demands for consequential and incidental damages, treble damages, and attorneys' fees and expenses. Combined, their claim demands excluding expenses and attorneys' fees total approximately $40,000,000.

17. The Defendants contend that Strongarm was "highly toxic" and failed to control weeds in their peanut crops. The Defendants also contend that Dow AgroSciences misrepresented the product as being "of a particular s'andard, quality, and grade" and that these

misrepresentations constituted false, misleading and deceptive acts and practices. Further, the Defendants allege false advertising, breach of warranty and statutory claims for alleged deceptive and fraudulent trade practices. The Defendants have demanded payment from Dow AgroSciences for certain damages, including consequential and incidental damages, treble damages and attorneys' fees and expenses.

18. The federally-approved Strongarm label sets forth "Terms and Conditions of Use," "Warranty Disclaimer," "Inherent Risks," and "Limitations of Remedies."

19. Dow AgroSciences contends that upon the individual Defendants' purchase, retention and use of Strongarm, contracts between the individual Defendants and Dow AgroSciences were created, with the text of the federally-approved Strongarm label supplying the terms of those contracts and defining the parties' respective rights and liabilities.

20. Due to the nature of the claims made against Dow AgroSciences, it is clear that the individual Defendants refuse to acknowledge the existence of such contracts and that they further refuse to acknowledge that the text of the federally-approved Strongarm label defines the parties' respective rights, obligations and liabilities upon Strongarm's failure to perform as Defendants claim they expected.

21. The Terms and Conditions of Use section provides that the purchaser should return the unopened package of Strongarm at once for a full refund if the Warranty Disclaimer, Inherent Risks of Use, and Limitations of Remedies are unacceptable to the purchaser. The Terms and Conditions also provide that use of the product constitutes acceptance of the terms of the label.

22. The Warranty Disclaimer provides "that th[e] product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label . . . . The Disclaimer also provides: "Dow AgroSciences makes NO OTHER EXPRESS OR IMPLIED WARRANTY OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY."

23. The Inherent Risks of Use section provides that risks such as crop injury are assumed by the buyer where abnormal conditions, e.g., drought, exist.

24. The Limitation of Remedies section provides as follows:

> The exclusive remedy for losses or damages resulting from the use of this product (including claims based on contract, negligence, strict liability, or other legal theories), shall be limited to, at Dow AgroSciences' election, one of the following:
>
> 1. Refund of purchase price paid by buyer or user for product bought, or
>
> 2. Replacement of amount of product used.
>
> Dow AgroSciences shall not be liable for losses or damages resulting from handling or use of this product unless Dow AgroSciences is promptly notified of such loss or damage in writing. In no case shall Dow AgroSciences be liable for consequential damages or incidental damages or losses.

The terms of the Warranty Disclaimer above and this Limitation of Remedies cannot be varied by any written or verbal statements or agreements. No employee or sales agent of Dow AgroSciences or the seller is authorized to

vary or exceed the terms of the Warranty Disclaimer of this Limitation of Remedies in any manner.

25. A controversy exists between Dow AgroSciences and the Defendants regarding the enforceability of these provisions on the federally-approved Strongarm label and the viability of Defendants' claims against Dow AgroSciences.

COUNT I

26. Dow AgroSciences incorporates by reference paragraphs 1 through 25 of its Complaint as if fully set forth herein.

27. Affixed to each container of Strongarm purchased by Defendants was a federally-approved label which contained a "Limitation of Remedies."

28. A limitation of remedies provision, such as the one included on the Strongarm label, is valid and enforceable pursuant to Tex. Bus. & Com. Code Ann. § 2.719.

29. Defendants have asserted a right to recover damages from Dow AgroSciences in an amount which exceeds that permitted by the Limitation of Remedies section in the federally-approved Strongarm label.

30. A justiciable controversy exists between Dow AgroSciences and Defendants regarding the rights and other legal relations of the parties with respect to the remedies available to the Defendants such that a declaration is necessary pursuant to 28 U.S.C. §§ 2201 and 2202.

31. Dow AgroSciences is entitled to a declaration that Defendants' available remedies, if any, are limited to those set forth in the Limitation of Remedies section of the federally-approved Strongarm label.

COUNT II

32. Dow AgroSciences incorporates by reference paragraphs 1 through 31 of its Complaint as if fully set forth herein.

33. Affixed to each container of Strongarm purchased by Defendants was a federally-approved label which contained a "Warranty Disclaimer."

34. A provision, such as the one included on the federally-approved Strongarm label, disclaiming express or implied warranties is valid and enforceable pursuant to Tex. Bus. & Com. Code Ann. § 2.316.

35. Defendants have asserted a right to bring claims for breach of express and implied warranties against Dow AgroSciences.

36. A justiciable controversy exists between Dow AgroSciences and Defendants regarding the rights and other legal relations of the parties with respect to the enforceability of the Warranty Disclaimer such that a declaration is necessary pursuant to 28 U.S.C. §§ 2201 and 2202.

37. Dow AgroSciences is entitled to a declaration that the Warranty Disclaimer section of the label is valid and enforceable.

COUNT III

38. Dow AgroSciences incorporates by reference the allegations contained in paragraphs 1 - 37.

39. Under the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § § 136-136y, all herbicides sold or distributed in the United States must be registered with the Administrator of the Environmental Protection Agency. The EPA also regulates both the design and content of the label for a registered herbicide. The final printed labeling for a herbicide must be submitted and

accepted by the Administrator before registration, and it is unlawful to sell an unregistered herbicide.

40. In determining the rights and legal relations of Dow AgroSciences and Defendants under the contract terms contained in the federally-approved Strongarm product label, this Court will be required to examine principles of federal preemption, which originate from the Supremacy Clause of the United States Constitution (U.S. Const., Art. VI, cl. 2), and issues of federal law and congressional intent, which originate from FIFRA.

41. The responsibility of the EPA to regulate the labeling and registration of herbicide products is inherently federal in character, and the availability of state law remedies with respect to unexpected consequences of use of a federally registered herbicide are governed by and limited by federal law.

42. Defendants have challenged the adequacy and sufficiency of Dow AgroSciences's federally-approved Strongarm product label by alleging claims for damages against Dow AgroSciences under theories of fraud, false advertising, misrepresentation, negligence in design, testing and marketing, breach of express and implied warranty and statutory claims for alleged deceptive and fraudulent trade practices.

43. At all times relevant hereto, Dow AgroSciences has sold the Strongarm herbicide with labels that were accepted by the EPA and affixed to the product at the time of the sale.

44. FIFRA contains an express preemption clause that provides that a state "shall not impose or continue in effect any requirements for labeling and packaging in addition to or different from those required under [FIFRA]." 7 U.S.C. § 136v(b). This provision expressly preempts Defendants' direct and indirect challenges to the adequacy and sufficiency of any EPA-approved herbicide labeling or packaging.

45. Defendants' claims are also impliedly preempted by federal law because they (1) conflict with FIFRA's regulatory scheme and (2) directly conflict with the express authority given to registrants – such as Dow AgroSciences – to "distribute or sell a registered product with the composition, packaging and labeling currently approved by the Agency." 40 C.F.R. § 152.130(a).

46. A justiciable controversy exists between Dow AgroSciences and Defendants regarding the rights and other legal relations of the parties with respect to federal preemption of the Defendants' claims such that a declaration is necessary pursuant to 28 U.S.C. §§ 2201 and 2202

PRAYER FOR RELIEF

For the foregoing reasons, Dow AgroSciences respectfully requests that the Court:

1. Declare that the Defendants' available remedies, if any, are limited to those set forth in the Limitation of Remedies section of the federally-approved Strongarm label; and

2. Declare that the Warranty Disclaimer section of the federally-approved Strongarm label is valid and enforceable;

3. Declare that the Plaintiff's and the Defendants' rights and obligations are governed by the federally-approved Strongarm label and any claims directly or indirectly attacking that federally-approved label, and/or the EPA approved composition of Strongarm, are expressly and implied preempted by federal statute and all regulations promulgated thereunder; and

4. Award any other relief that the Court deems just and proper.

JURY DEMAND

Plaintiff Dow AgroSciences LLC respectfully demands a jury trial on all claims and issues.

Dated: April 15, 2002

Respectfully submitted,

McCLESKEY, HARRIGER, BRAZILL & GRAF, L.L.P.

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ATTORNEYS FOR PLAINTIFF
DOW AGROSCIENCES LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC, Plaintiff,	)	
v.	)	Civil Action No. 5-01CV0331-C
DENNIS BATES, [*et al.*], Defendants.	)	

[Filed Apr. 23, 2002]

DOW AGROSCIENCES' ANSWER TO DEFENDANTS' ORIGINAL COUNTERCLAIM

Dow AgroSciences LLC ("DAS") respectfully submits the following Answer and Affirmative Defenses to Defendants' Original Counterclaim:

Answer

I.

With respect to the allegations contained in the first rhetorical paragraph of Section I of Defendants' Original Counterclaim, DAS admits only that the persons and entities listed in rhetorical paragraph 1 of Section I of Defendants' Original Counterclaim are those persons and entities that attempt to assert a counterclaim against DAS. With respect to the allegations contained in the second rhetorical paragraph of Section I of Defendants' Original Counterclaim, DAS admits only that it is a Delaware Limited Liability Company with a principal place of business in the State of Indiana.

II.

DAS admits that Defendants/Counter-Plaintiffs herein are farmers who now own or in the past have owned and operated lands and peanut farms. DAS denies all remaining allegations that may be set forth in the remainder of the only rhetorical paragraph that comprises Section II of Defendants' Original Counterclaim.

III.

DAS denies all allegations set forth against it in the two rhetorical paragraphs that comprise Section III of Defendants' Original Counterclaim.

IV.

DAS denies all allegations set forth against it in the eight rhetorical paragraphs that comprise Section IV of Defendants' Original Counterclaim.

V.

DAS states that the terms of the Strongarm label speak for themselves. DAS denies all allegations set forth against it in the two rhetorical paragraphs that comprise Section V of Defendants' Original Counterclaim.

VI.

DAS states that the terms of the Strongarm product label speak for themselves. DAS denies all allegations set forth against it in the seven rhetorical paragraphs that comprise Section VI of Defendants' Original Counterclaim.

VII.

DAS is without information at present concerning whether, in fact, each of the Counter-Plaintiffs purchased or applied Strongarm herbicide. DAS denies all remaining allegations set forth against it in the two rhetorical paragraphs that comprise Section VII of Defendants' Original Counterclaim.

VIII.

DAS is without information at present concerning what, if any, statements were made by local Strongarm retailers. DAS is also without information at present concerning whether Counter-Plaintiffs ever relied on any representations whatsoever in connection with the alleged purchase of Strongarm herbicide. DAS denies all remaining allegations set forth against it in the three rhetorical paragraphs that comprise Section VIII of Defendants' Original Counterclaim.

IX.

DAS is without information at present concerning what, if any, statements were made by local Strongarm retailers. DAS is also without information at present concerning whether Counter-Plaintiffs ever relied on any representations whatsoever in connection with the alleged purchase of Strongarm herbicide. DAS denies all remaining allegations set forth against it in the three rhetorical paragraphs that comprise Section IX of Defendants' Original Counterclaim.

X.

DAS denies the allegations set forth against it in the rhetorical paragraph that comprises Section X of Defendants' Original Counterclaim.

XI.

DAS denies the allegations set forth against it in the first rhetorical paragraph that comprises Section XI of Defendants' Original Counterclaim.

XII.

DAS denies the allegations set forth against it in the rhetorical paragraph that comprises Section XII of Defendants' Original Counterclaim.

WHEREFORE, DAS respectfully requests that Defendants/Counter-Plaintiffs take nothing against it by way of their Original Counterclaim, and for all other proper relief.

II.

Affirmative Defenses

1. Defendants' counterclaims against DAS are expressly preempted by the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136, *et seq*.

2. Defendants' counterclaims against DAS are impliedly preempted by FIFRA.

3. Defendants' counterclaims against DAS are preempted because the United States Environmental Protection Agency ("EPA") granted it express permission to distribute and sell its product with the labeling, packaging and composition as approved by the EPA. 40 C.F.R. § 152.130(a).

4. DAS effectively has disclaimed all implied warranties of merchantability or fitness for a particular purpose, together with any other express or implied warranties other than those specifically stated on the product label, subject to the inherent risks of use also disclosed on the product label.

5. DAS effectively has limited available remedies resulting from damages associated with the use of the product to a refund of the purchase price or replacement of the amount of product used, at DAS's sole election.

6. DAS effectively has disclaimed all liabilities for consequential or incidental damages or losses.

7. DAS effectively has precluded any assertion by Defendants of any alleged statement and/or representation and/or agreement made by DAS or any of its agents or representatives as a means to avoid the disclaimers of

warranties and limitations of remedies stated on the product label.

8. Defendants' counterclaims are precluded by the economic damages rule.

9. Defendants' alleged damages were proximately caused or materially contributed to by Defendants' own actions and/or negligence or the actions and/or negligence of Defendants' agents or representatives.

10. Defendants' alleged damages were proximately caused or materially contributed to by the actions and/or negligence of party(ies) and/or individual(s) over whom DAS had no control or right of control.

PRAYER

WHEREFORE, DAS respectfully requests that Defendants/Counter-Plaintiffs take nothing against it by way of their Counterclaim, and for all other proper relief.

Respectfully submitted,

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action
	)	No. 5-01CV0331-C
DENNIS BATES, [*et al.*],	)	
	)	
Defendants.	)	

[Filed June 14, 2002]

DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION FOR RECONSIDERATION OF SUMMARY JUDGMENT

Respectfully submitted,

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BY: /s/ Phil Watkins
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ATTORNEYS FOR DEFENDANTS

[Text Omitted, Exhibits Excerpted]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action
	)	No. 5-01CV0331-C
DENNIS BATES, [*et al.*],	)	
	)	
Defendants.	)	

AFFIDAVIT OF JOHN M. BROWN, Ph.D.

THE STATE OF MISSOURI

COUNTY OF BOONE

Before me, the undersigned notary public, on this day personally appeared JOHN M. BROWN, PH.D., who, after being on his oath duly sworn, deposed as follows:

1. My name is John M. Brown. I am over the age of 21 years and I am competent to make this affidavit. I have never been convicted of a felony and I have personal knowledge of the facts stated herein due to my education, training, experience and personal viewing. All of the facts stated in this affidavit are true and correct.

2. My address is 7900 O'Neal Road, Columbia, Missouri 65202. I have a Bachelor of Science in Agriculture Business from East Texas State University, a Masters of Science Degree in Floriculture from Texas A&M University and a Doctorate Degree in Horticulture from North Carolina State University. In my undergraduate and graduate education I took courses in general horticulture, orchard management, plant

physiology, plant nutrition, plant entomology and plant pathology. During the course of my graduate education, I conducted field investigations including the evaluation and analysis of herbicide damage upon plants under the direction of Dr. Ed McWilliams at Texas A&M University.

3. After receiving my doctorate degree in horticulture in 1987, I was employed with the University of Missouri and the Missouri Agricultural Extension Service. My duties included giving horticulture advice and assistance to farmers and growers. I taught courses on plant disorders to growers and performed on-site consultations with growers, chemical companies and the Missouri Agricultural Extension Service.

4. From January, 1989 to August, 1993, I was an assistant professor of horticulture in the Department of Plant Science at the University of Missouri-Columbia. My duties included working with the Agricultural Extension Service and working with the plant laboratory studying plant disorders. As a part of my study in the plant laboratory studying plant disorders, we evaluated and analyzed herbicide damage upon plants in a laboratory and farm setting. I also taught classes at the University of Missouri in Horticulture.

5. In September, 1993, I founded Agricultural Investigation and Research Corp. (AIR, Corp.). AIR, Corp. serves as a consultant in the investigation of plant disorders chiefly related to pesticide and herbicide damage. AIR, Corp. is located at 7900 O'Neal Road, Columbia, Missouri.

6. When asked to determine the causes of plant disorder in peanut crops, I have been taught in my undergraduate and graduate education to begin with the history of the peanut farms which includes oral information from the farm owner, manager and other persons who are familiar with the farm and the accumulation of written information concerning the soils,

irrigation water, horticulture practices, including fertilizer program, weed management program, pesticide program, fungicide program, general farm management and peanut production. After gathering this information, I conduct a visual inspection of the farm to observe any symptoms upon the peanut plants. The inspection of the peanut farm includes gathering peanut plants, soil and water for laboratory analysis, taking photographs and video of the farm, plants and farm operations. On the peanut plant itself, I will examine the leaves, stem, seed and roots. The investigation inspection methods which I have outlined above have been taught to me in the various horticulture courses that I have taken in my undergraduate and graduate education.

7. Based on my study of the Dow AgroSciences LLC herbicide Strongarm together with research that I have done with its label instructions together with my studies, I am familiar with it's mode of action. The active ingredient in Strongarm is diclosulam. Diclosulam is a member of the Triazolopyrimidine sulfonanilide family of herbicides. The mode of action for diclosulam in plants is the inhibition of the enzyme acetolactate synthase (ALS). This enzyme catalyzes the first step in branch-chain (essential) amino acid biosynthesis. This pathway leads to the synthesis of valine, leucine and isoleucine and is unique in plants. Blocking this pathway deprives the plant of these essential amino acids, thus interferes with DNA synthesis and cell growth leading to plant destruction. ALS herbicides are absorbed by the roots, shoots and foliage and translocate throughout the plant in the xylem and phloem. ALS herbicides accumulate in the meristematic growing points of the plant such as the apical buds at the tips of roots, shoots leaf axils and reproductive structures. Inhibition of plant growth will occur rapidly but visible symptoms of plant response may not show up for one to three weeks depending on the plant species, soil activity and environmental conditions.

8. Beginning in the spring of 2001, I was contacted by numerous farmers and peanut growers with complaints that their 2001 crops of wheat, corn and cotton were not growing in a normal fashion following the use of Strongarm in the growing year 2000 for peanuts. As I began to evaluate these complaints, the farmers and growers provided me with photographs, videotapes and verbal descriptions of the appearance of their 2000 peanut plants and crops. In addition, I visited Comanche Horizon Corporation's farm in Gaines and Andrews Counties and visited at least twenty farms in Oklahoma. The physical description of plant injury was similar in west Texas and in Oklahoma. The photographs and videotape taken of peanuts from various west Texas farms and Oklahoma farms were similar. The descriptions and physical appearance of injury to peanut plants included severe growth inhibition, crop yellowing (chlorosis), root injury, root necrosis (death), severe stunting of the plant throughout the growing season, failure of the peanuts to overlap in the rows and reduced yield and production.

9. Based on my research, typical soil and water pH in the peanut farming regions of west Texas is 7.0 and above. There is good scientific evidence which I believe suggests that injury to the 2000 peanut crop resulted from high pH of the soil and irrigation water causing a greater availability of diclosulam in the plant-root environment.

10. As part of my efforts to determine what information, studies or data Dow AgroSciences LLC had submitted to the Environmental Protection Agency (EPA), I contacted the EPA. I spoke with Jim Tompkins, Product Manager 25, Herbicide Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460. Mr. Tompkins is the product registration representative for diclosulam, which is the active ingredient in Strongarm®. I have been attempting since February, 2002 to gather information from the EPA about

Dow AgroSciences LLC's submission of efficacy studies, data and phytotoxicity studies to the EPA but have been unable to get this information until June 11, 2002. When I spoke with Mr. Tompkins about any submission of data or studies to the EPA, he informed me that Dow AgroSciences LLC had not submitted any target area phytotoxicity studies or data on peanuts treated with diclosulam (Strongarm®). He further told me that EPA did not require Dow AgroSciences LLC to submit data concerning target area phytotoxicity for peanuts. He told me that the EPA had chosen not to require submission of studies and data relating to the efficacy of products including Strongarm®. Efficacy refers to how well a product works. Mr. Tompkins informed me that the EPA did not evaluate whether diclosulam (Strongarm®) had a toxic effect on peanut plants. On my own I verified this fact through review of filings with the EPA that Dow AgroSciences LLC did not submit any data or studies to the EPA on whether diclosulam (Strongarm®) had a toxic effect on peanut plants.

Further Affiant sayeth naught.

/s/ John M. Brown
JOHN M. BROWN, PH.D.

[Notary Omitted]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC,	)	[Stamp Omitted]
	)	
Plaintiff,	)	
v.	)	Civil Action No.
	)	5-01CV0331-C
DENNIS BATES, *et al.*,	)	
	)	
Defendants.	)	

[Filed July 5, 2002]

PLAINTIFF DOW AGROSCIENCES LLC'S RESPONSE TO DEFENDANTS' MOTION FOR RECONSIDERATION

Respectfully submitted,

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ATTORNEYS FOR PLAINTIFF
DOW AGROSCIENCES LLC

[Text Omitted, Exhibits Excerpted]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 5-01CV0331-C
	)	
DENNIS BATES, *et al.*,	)	
	)	
Defendants.	)	

AFFIDAVIT OF JOHN J. JACHETTA, Ph.D.

John J. Jachetta, Ph.D., being duly sworn, deposes and says:

1. My name is John J. Jachetta. I am an adult, over the age of 21 years and I am competent to testify as to all matters stated herein.

2. I am employed by Dow AgroSciences LLC ("Dow AgroSciences") as Regulatory Leader in Regulatory Success - Americas. From September 1997 to March 2000, I was the Registration Manager for, among others, Strongarm• herbicide. I am familiar with the facts and circumstances discussed herein, which are based upon personal knowledge and upon review of business records of Dow AgroSciences.

3. As Registration Manager for Strongarm herbicide, I was responsible for all matters concerning the federal registration of Stongarm herbicide pursuant to the Federal Insecticide, Fungicide and Rodenticide Act

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• Trademark of Dow AgroSciences LLC.

("FIFRA"). I am familiar with the regulations promulgated and enforced pursuant to FIFRA by the Environmental Protection Agency ("EPA") and other applicable federal laws and regulations.

4. My responsibilities as Registration Manager included assuring that Dow AgroSciences fully complied with applicable EPA requirements and regulations concerning the federal registration of Strongarm herbicide.

5. The EPA accepted the product label for Strongarm herbicide on March 8, 2000, and assigned registration number 62719-288. Attached hereto as **Exhibit A** is a true and accurate stamped copy of the EPA's acceptance and the accepted product label. The acceptance was conditioned upon Dow AgroSciences submitting the data listed therein, which Dow AgroSciences thereafter submitted.

6. At all times relevant hereto, Dow AgroSciences sold Strongarm herbicide only with EPA-accepted labels affixed to the product at the time of the sale. A true and accurate copy of the product label in effect during the time period relevant to the claims involved in the above-referenced lawsuit bears Label Code D02-044-003 and is attached hereto as **Exhibit B**.

7. By its acceptance of the product label for Strongarm herbicide, the EPA determined that the data submitted by Dow AgroSciences in support of its registration complied with all FIFRA requirements.

8. Title 40, Section 158 of the Code of Federal Regulations provides a sampling of some of the areas with respect to which registrants submit data to the EPA in connection with the registration of herbicides. Among those areas include: residue chemistry (40 C.F.R. §158.20(c), §158.202(c) & -.240), environmental fate (40 C.F.R. §158.202(d) & -.290), non-target organisms and plant protection (40 C.F.R. §158.202(h) & -.540), and product performance (40 C.F.R. §158.202(i)).

9. The FIFRA Section 3 registration application for Strongarm herbicide and its active ingredient, diclosulam, was made under what is commonly called the Reduced-Risk Initiative. The criteria for the Reduced-Risk Initiative are published on September 4, 1997 in Pesticide Registration Notice 97-3, entitled "Guidelines for Expedited Review of Conventional Pesticides under the Reduced-Risk Initiative and for Biological Pesticides." EPA's priorities for expedited review are further detailed in PR-Notice 98-7.

10. To initiate the Reduced Risk review process, an applicant must submit an application called a Reduced Risk Rationale before and in addition to what the EPA requires in the FIFRA Section 3 data package. The Reduced Risk Rationale must demonstrate how the use of the pesticide may reasonably be expected to accomplish one or more of the criteria listed in FIFRA Section 3(c)(10). Included in those criteria is the "reasonable expectation" that a pesticide may: (1) reduce the risks of pesticide to non-target organisms; (2) reduce the potential of contamination of environmental resources; or (3) make pest management strategies more effective.

11. Reduced Risk Rationales must fully address all of the following areas: (a) executive summary, (b) human health effects; (c) environmental fate and effects; (d) other hazards; (e) risk discussion (f) pest resistance and management (e.g., IPM); (g) comparative performance (efficacy), and (h) other information and how application complies with FQPA.

12. Because Strongarm herbicide was submitted for registration pursuant to the Reduced-Risk Initiative and pursuant to the specific data requirements outlined in 40 CFR §158.540, the EPA required all of the above-referenced materials, including efficacy and terrestrial plant phytotoxicity/injury.

13. Pursuant to Section VII of PR-Notice 97-3, the "comparative performance data" in the Reduced Risk Rationale is, in fact, efficacy data. The EPA reviews such efficacy data to assure that risk reduction has a reasonable opportunity to be accomplished by adoption of the new pesticide by growers. There are two types of data that satisfy the Section G efficacy requirements: (1) Summaries of comparative performance data in which the performance of the candidate pesticide is compared to that of alternative control measures under actual-use or simulated actual-use conditions; and (2) Summaries of the available efficacy data if comparative performance data are not available. EPA requires data summaries to include statistical analysis of significant differences between the new pesticide and the commonly used alternatives. Dow AgroSciences' Reduced Risk Rationale included both types of data summaries.

14. Based upon my 7 years dealing with the EPA, my regulatory experience, and EPA guidelines, the EPA uses phytotoxicity/plant injury data to assess the potential hazard of pesticides on nontarget plants including crops, ornamentals and others that are intentionally sprayed or exposed outside of the area of intended application. More specifically, guidelines for EPA Pesticide Assessment, Subdivision J 122-1 and 123-1 seed germination/seedling emergence and vegetative vigor tests evaluate ten plant species, including 6 dicot species representing four plant families and four monocot species representing two plant families. The list of ten test species is required to contain corn as a representative monocot, soybeans as a representative legume dicot as well as a dicot root crop species; the remaining seven species are assembled from plant families containing commonly grown crop plants. The distribution species is representative of crop species in the agricultural environment.

15. Dow AgroSciences submitted plant phytotoxicity/ crop injury and environmental fate data, along with the

above-referenced data and efficacy studies. By way of example, Dow AgroSciences' submission to the EPA for diclosulam included studies evaluating the effects of Strongarm on Seedling emergence and vegetative vigor of non-target terrestrial plants, the phytotoxicological effects of Strongarm and its soil degradates. The Dow AgroSciences' submission to the EPA also included an ecological risk assessment, a study examining the magnitude of residue in processed products of peanuts, the reasonable grounds in support of the petition for the establishment of a tolerance for diclosulam on peanut nutmeat, the magnitude of residues of Strongarm in peanuts, and a summary of the environmental fate of Strongarm.

FURTHER, the affiant sayeth not.

Dated: July 1, 2002

/s/ John J. Jachetta
John J. Jachetta, Ph.D.

[Notary Omitted]

EXHIBIT A

[EPA Notice of Registration – reproduced at pp. 63-93, *supra*]

EXHIBIT B

[Dow AgroSciences Specimen Label for Strongarm – reproduced at pp. 94-112, *supra*]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

[Stamp Omitted]

DOW AGROSCIENCES LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No.
	)	5-01CV0331-C
DENNIS BATES, *et al.*,	)	
	)	
Defendants.	)	

ORDER GRANTING PLAINTIFF DOW AGROSCIENCES LLC'S MOTION FOR RETURN OF FUNDS INVESTED IN REGISTRY OF COURT

Before this Court is Plaintiff Dow AgroSciences LLC's Motion for Return Of Funds Invested In Registry Of Court And Brief In Support. After considering all relevant arguments and evidence, the Court **GRANTS** Plaintiff's motion.

Plaintiff Dow AgroSciences has previously tendered the following funds for deposit into the registry of the Court with the Court Registry Investment System (CRIS), administered through the United States District Court for the Northern District of Texas, as custodian:

Dennis Bates	$1,653.44
Jimmy Burson	$1,417.20
Benny Judah/Clearwater Farms, Inc.	$2,834.46
Tommy Coleman	$9,520.00
Richard Cox	$ 712.26
Wayne Davis	$2,834.46
Burk Denman	$1,542.40

Neil Friessen	$3,769.20
Jake Froese	$1,884.60
Thomas Fuston	$9,200.00
Arthur Galvan/G-5 Partnership	$4,240.35
Greg Hughes	$ 942.30
Sandra Hughes/Karl Don Hughes/ JH Cattle Co.	$1,884.60
Rudy Klassen	$ 708.62
Ronnie Love	$3,732.04
Kevin Mathis	$1,189.12
Brad Palmer	$4,724.10
Jerry Parrish	$2,883.60
JoEvelyn Patterson/Donald Gruben/ Sheila Gruben/ Gruben Farms	$2,362.05
Stacy Price	$2,760.00
Benny Judah/Progressive Farms	$2,834.46
Morris Rushing/Pea-Cot Farms	$3,015.90
Billy Shannon	$2,055.38
Craig West	$1,872.00
Frenchie Lee Wheeler	$ 708.62

IT IS THEREFORE ORDERED that the Clerk of the Court issue a check payable to Dow AgroSciences LLC which represents a refund of the monies listed above, together with any accrued interest. The Clerk shall tender Dow AgroSciences LLC's refund check to its attorney of record, Mr. Fernando M. Bustos.

IT IS FURTHER ORDERED that CRIS is authorized and directed to deduct the proper registry fee determined on the basis of the rates published by the Director of the Administrative Office, as approved by the Judicial Conference.

SIGNED this 4th day of November, 2003.

/s/ Sam R. Cummings
SAM R. CUMMINGS
UNITED STATES DISTRICT JUDGE

[Seal Omitted]

U.S. Environmental Protection Agency

Pesticides: Regulating Pesticides

Pesticide Registration (PR) Notice 96-4

June 3, 1996

Pesticide Registration (PR) NOTICE 96-4

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Federal Registration and Reregistration of Pesticide Products

SUBJECT: Label Statements Involving Product Efficacy and Potential for Harm to Property

I. INTRODUCTION

This notice explains EPA procedures in approving pesticide labels that include claims relating to the efficacy of agricultural pesticides and provides a warning to growers regarding reliance on label statements regarding pesticide efficacy. EPA is issuing this notice at this time to correct a misunderstanding regarding the FIFRA label approval process and efficacy claims that is reflected in a series of court decisions concerning the preemptive effect of FIFRA.

II. LEGAL FRAMEWORK

A. Registration and the Label Approval Process

EPA approves pesticide labels in the process of registering a pesticide under FIFRA. FIFRA specifies that EPA shall register a pesticide if:

(1) its composition is such as to warrant the proposed claims for it;

(2) its labeling and other material required to be submitted comply with the requirements of this Act;

(3) it will perform its intended function without unreasonable adverse effects on the environment; and

(4) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

7 U.S.C. 136c (c) (5). Although the first registration requirement identified above mandates that EPA consider efficacy of label claims, Congress, in 1978, explicitly gave EPA the authority to waive that requirement. FIFRA states:

> In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy.

7 U.S.C. 136c(c)(5). The legislative history explains that Congress believed that product performance issues for agricultural pesticides were adequately addressed by information from government and university sources and market forces:

> This authority [to waive efficacy data] will be used most commonly with respect to agricultural pesticides, due to the high level of knowledge concerning pesticidal efficacy that prevails in the agricultural community, the existence of means for communicating efficacy information to users, the organizational expertise of the Department of Agriculture, the extension services, and the universities in this area,

and the stake the industry has in marketing products that are efficacious.

S. Rpt. 95-334, 95th Cong., 1st Sess. 20 (July 6, 1977).

EPA has acted under this authority to waive, by regulation, data requirements as to efficacy issues for all agricultural pesticides. 44 Fed. Reg. 27932, 27938 (col. 3) (May 11, 1979); 40 CFR 158.640(b)(1); see also 47 Fed. Reg. 57624 (December 27, 1982). EPA concluded that agriculture pesticides are "effectively regulated by the marketplace," 44 Fed. Reg. 27932, 27938 (col. 3) (May 11, 1979), and that waiving review of the efficacy of agricultural pesticides in the registration process would enable the Agency to focus of its "primary mandate under FIFRA": investigating "the health and safety aspects of pesticides." 47 Fed. Reg. 53192 (November 24, 1982); 47 Fed. Reg. 40659, 40661 (col.1) (September 15, 1982). EPA pointed to private legal actions for damages as one factor that would ensure that pesticide manufacturers sold an efficacious product: "pesticide producers are aware that they are potentially subject to damage suits by the user community if their products prove ineffective in actual use." 47 Fed. Reg. 40659, 40661 (col.2) (September 15, 1982).

EPA has also, by regulation, promulgated various requirements pertaining to pesticide labels. These regulations bar the registration of any pesticide with a misbranded label, 40 C.F.R. 152.112(f), and contain specific examples of label statements that are considered false or misleading and thus render a label misbranded. 40 C.F.R. 156.10(a)(5). Additionally, the regulations have requirements for warning statements and mandate that pesticide products have adequate use directions. 40 C.F.R. 156.10(h) and (i).

B. State Preemption Under FIFRA

FIFRA permits states broad authority to regulate pesticides but makes it unlawful for states that undertake such regulation to "impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this Act." 7 U.S.C. 136v(b). A number of federal court decisions have held that this preemption of state authority as to pesticide labels bars damage claims in state court by growers against pesticide manufacturers. The courts have reasoned that allowing such a claim by a grower would be, in effect, permitting the state to impose label requirements "in addition to or different from" the federally-approved label.

III. LABEL APPROVAL AND PESTICIDAL EFFICACY

There have been several recent preemption decisions involving claims by growers concerning pesticidal efficacy or property damage caused by a pesticide. For example, in Taylor Ag Industries v. Pure-Gro, 54 F.3d 555 (9th Cir. 1995), several growers sued the manufacturers and distributor of a pesticide that the growers alleged had damaged their cotton crop even though they had applied the pesticide according to the label directions. The court denied the growers' claims on the ground that allowing recovery of damages would interfere indirectly with EPA's "rigorous label-approval process." Id. at 560. In Welchert v. American Cyanamid, Inc., 59 F.3d 69 (8th Cir. 1995), and Worm v. American Cyanamid, Inc. 5 F.3d 744 (4th Cir. 1993), growers sued a pesticide manufacturer seeking recovery for harm to crops allegedly caused when the manufacturer's herbicide remained in the soil and damaged rotated crops. Both courts dismissed the growers' claims noting that EPA's labeling regulations required instructions on rotational crop restrictions. The courts reasoned that to permit such lawsuits "would be to allow state courts to sit, in effect, as super-EPA review

boards that could question the adequacy of the EPA's determination of whether a pesticide registrant successfully complied with the specific labeling requirements of its own regulations." Welchert, 59 F.3d at 73; Worm, 5 F.3d at 749.

These court decisions are based on the premise that, in approving labels for agricultural pesticides, EPA examines, or at least has the obligation to examine, the efficacy of the pesticide and related issues such as the potential for the pesticide to cause property damage. The courts, however, have not taken into account the plain language of the statute on this issue and have misinterpreted the thrust of EPA's regulations. As noted above, in actual fact, EPA, with Congress' approval, stopped evaluating pesticide efficacy for routine label approvals almost two decades ago. Further, as explained below, EPA's regulations do not require a review of efficacy of property damage issues for agricultural pesticides.

EPA's labeling regulations must be interpreted in light of the statutory requirements for registration and EPA's waiver of the requirement for efficacy data on agricultural pesticides. Because efficacy data is not reviewed as part of the registration of agricultural pesticides, it would be incorrect to contend that the label approval process involves an examination of the efficacy of the pesticide. Rather, the label approval process is centered on the issue of the whether label, including the specification of use sites and the directions for use on the label, meets the core requirement for registration: that the pesticide not cause "unreasonable adverse effects on the environment." That term is defined as "any unreasonable risk to man or the environment . . . ." 7 U.S.C. 136(bb). Accordingly, the primary focus in the label approval process for agricultural pesticides involves assessing and regulating the potential risks to humans and the environment posed by such pesticides.

To this end, EPA applies the requirements in its labeling regulations with an eye to risk not efficacy issues. This is illustrated by how EPA applies label requirements regarding pesticide use sites and directions for the use of pesticides including directions concerning rotational crops. Label regulations require that pesticide use sites (e.g., specific crops, animals, etc.) be listed on the label because assessment of the dietary risk of pesticides is based on the foods that legally may contain the pesticide, and, under FIFRA, the label establishes the legal limits on use of a pesticide. 7 U.S.C. 136j(a)(2)(G). Use sites are not reviewed as to the pesticide's efficacy for those crops. The label regulations address the directions for use of a pesticide for the purpose of insuring that pesticide applicators and farmworkers are adequately protected. Additionally, directions for use establish legal limits as to the amounts of pesticide that may be applied and thus allow EPA to control and estimate dietary exposure. EPA does not check to see whether application equipment mentioned in directions for use will be harmed or whether other property damage might occur. For example, the label regulations on directions for use specify that rotation crop restrictions are required when needed "to prevent unreasonable adverse effects upon the environment." 40 C.F.R. 156.10(i)(2)(x). Such restrictions are needed for certain pesticides to prevent uptake of residual pesticide residues from the soil into crops for which the pesticide is not registered. EPA's concern is that the consumption of the rotated crop would increase dietary exposure to the pesticide residue. Rotational crop restrictions are not reviewed to determine if the rotated crop would be injured by the residual pesticide residues.

An additional requirement for registration, noted above, is that the pesticide's labeling comply with the Act. Separately, EPA, by regulation, has required that labeling not be misbranded. 40 C.F.R. 152.112(f). However, these registration requirements should not be read as reintroducing efficacy concerns into the label approval

process. Having directly given EPA the authority to disregard efficacy issues, Congress could not have intended that, once EPA exercised this authority, the same efficacy issues would come in through the back door of the label approval process. Under the statute and its regulations, EPA still must determine in registering a pesticide if the pesticide's label complies with FIFRA or is misbranded but, unless EPA reinstates the requirement to submit efficacy data (either generally or with regard to a particular pesticide), that compliance and misbranding inquiry will generally not extend to the evaluation of the efficacy of the pesticide.

Efficacy and property damage issues are at times relevant to the continued registration of a pesticide. FIFRA's "unreasonable adverse effects" standard requires EPA to take into account "economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. 136(bb). A pesticide's efficacy and its potential to cause property damage are factors to be considered in determining the economic benefit a pesticide provides to farmers. However, in light of EPA's waiver of the efficacy data requirement for initial registration, these issues would generally only arise following the registration of the pesticide, including approval of the pesticide label. For example, if a pesticide manufacturer were to learn that one its registered pesticides was causing property damage, the manufacturer would be obligated to report that information under section 6(a)(2) of the statute. 7 U.S.C. 136c(a)(2). Additionally, if EPA discovers new risk concerns with an already-registered pesticide, it might examine efficacy data with regard to the pesticide in making an evaluation under the unreasonable adverse effects standard to determine if the product's registration should be cancelled or suspended.

IV. CONCLUSION

EPA hopes this Notice will be useful to courts, the regulated community, and pesticide users. EPA believes this Notice should be helpful to courts in preemption cases that involve EPA's labeling regulations. For example, some courts have mistakenly assumed that EPA's labeling regulations concerning the directions for use of a pesticide have an efficacy component. Further, other courts have erroneously concluded that because a pesticide label contained warnings regarding property damage that EPA had necessarily evaluated such warnings and found them to be truthful and adequate. As to registrants and applicants for registration, this Notice is intended to confirm that EPA has not altered its regulation relating to the waiver of efficacy data requirements for the registration of agricultural pesticides. Finally, as to pesticide users this Notice is intended to clarify that EPA's approval of a pesticide label does not reflect any determination on the part of EPA that the pesticide will be efficacious or will not damage crops or cause other property damage.

Daniel M. Barolo
Director, Office of Pesticide Programs

[Seal Omitted]

U.S. Environmental Protection Agency

Pesticides: Regulating Pesticides

Pesticide Registration (PR) Notice 97-3

September 4, 1997

Pesticide Registration (PR) Notice 97-3

NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Registration of Pesticide Products

SUBJECT: Guidelines for Expedited Review of Conventional Pesticide under the Reduced-Risk Initiative and for Biological Pesticides

I. PURPOSE

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended by the Food Quality Protection Act of 1996 (FQPA) requires the Environmental Protection Agency (EPA) to develop procedures and guidelines for expedited review of any pesticide. These procedures and guidelines must be in place within one year after the date of enactment of the FQPA (by August 3, 1997). EPA has already established a Reduced Risk Initiative for conventional pesticides, has formed the Biopesticides and Pollution Prevention Division to review biological pesticides and has established the Antimicrobial Division to review antimicrobial pesticides. The purpose of this PR Notice is to provide the process and criteria to guide applicants in developing their submissions to these programs.

This PR Notice supersedes the reduced-risk criteria published in Federal Register Notices 57 FR 32140, July 20, 1992 and 58 FR 5854, January 22, 1993 and PR Notice 93-9, July 21, 1993. In addition, it defines the types of pesticide products reviewed by the Biopesticides and Pollution Prevention Division and describes how an applicant can apply for biochemical pesticide classification.

The goal of the Reduced-Risk Pesticide Initiative and the Biopesticides and Pollution Prevention Division is to encourage the development, registration and use of lower-risk pesticide products which would result in reduced risks to human health and the environment when compared to existing alternatives. The major incentive which EPA offers for these pesticides is expedited registration review. The major goal of the Antimicrobial Division is to provide expedited review of all types of antimicrobial registration actions.

II. APPLICABILITY

This notice applies to all applicants for initial registration and amended registration for conventional pesticides, as described more fully in Sections IV-X, and for biological pesticides, as described in Section XI. The term "conventional pesticides" as used in this notice includes all pesticides other than biological pesticides and antimicrobial pesticides (as defined in FQPA). Since certain pesticide products, such as wood preservatives and antimicrobials, are not defined as antimicrobial products in FQPA but are handled in the Antimicrobial Division, for the purposes of this notice they are considered conventional pesticides.

III. EFFECTIVE DATE

This PR Notice is effective immediately.

IV. BACKGROUND ON THE REDUCED-RISK INITIATIVE

In July 1992, the Office of Pesticide Programs (OPP) published a Federal Register notice announcing the need for incentives for the development and registration of reduced-risk pesticides. In a subsequent Federal Register notice (January 1993) OPP announced the initiation of the Reduced-Risk effort, and in July 1993 OPP published PR Notice 93-9 which provided interim reduced-risk criteria and guidance for submissions.

Since July 1993, applicants have sent thirty-nine new chemical or new use submissions to OPP for consideration as reduced-risk pesticides. Of the thirty-nine, twenty-two have been accepted by OPP as reduced-risk candidates; and sixteen have been rejected. Of the twenty-two accepted reduced-risk submissions, fourteen have been registered. The following is a list of the registered pesticides by accepted common names (if available) and their trade name (in parenthesis):

(1) Hexaflumuron (Recruit) – below ground bait station termiticide

(2) Flumiclorac-pentyl (Resource) – post emergent herbicide on corn, soybeans

(3) Methyl Anthranilate (Rejex-It) – bird repellent on cherries, grapes, blueberries, forestry

(4) Tebufenozide (Confirm) – insecticide on walnuts

(5) Hymexazol (Tachigaren) – fungicide seed treatment on sugar beets

(6) Fludioxonil (Maxim) – fungicide seed treatment on corn, sorghum

(7) (Cadre) – herbicide on peanuts

(8) (Mefenoxam) – fungicide on multiple crops

(9) Spinosad (Spinosad) – insecticide on cotton

(10) Azoxystrobin (Heritage) – fungicide on turf

(11) Alpha-Metolachlor (CGA 77102) – herbicide on multiple crops.

(12) Hexaflumuron (Recruit) – above ground bait station new use termiticide

(13) Imazamox (Raptor) – herbicide on soybeans

(14) Azoxystrobin (Heritage) – fungicide on grapes, bananas, peaches, tomatoes, pecans and peanuts

The major advantage for reduced-risk pesticides is expedited registration review. For FY95 and FY96 (prior to the passage of FQPA in August 1996) the average total time required to register a new conventional pesticide was thirty-eight months. For reduced-risk pesticides the average total time for registration was only fourteen months. Since passage of FQPA three new AI, reduced-risk pesticides were registered in seventeen, eighteen and seventeen months, somewhat longer than the pre-FQPA average but still substantially shorter than the conventional pesticide times. The faster registration times reflect, in part, the expedited review status granted reduced-risk actions. Not only is the initial submission granted a high review priority but also any resubmission that may be necessary.

If the applicant is simultaneously seeking registration in Canada, and if the application has been determined by Canada to be complete, the reduced-risk action can also qualify for work-sharing between the two countries. While this work-sharing program is still in the "pilot" stage, it could result in further reduced review times and greater harmonization.

V. CHARACTERISTICS OF ACCEPTABLE AND UNACCEPTABLE SUBMISSIONS FOR THE REDUCED-RISK INITIATIVE

OPP has assessed fourteen of the twenty-two reviews conducted by the Reduced Risk Committee of submissions that were determined to be reduced-risk. Those factors that most significantly contributed to EPA's decision to grant reduced risk status are summarized below in descending order:

- human health effects
  - very low mammalian toxicity
  - toxicity generally lower than alternatives (10-100X)
  - displaces chemicals that pose potential human health concerns [e.g., organophosphates (OPs), probable carcinogens (B2s)]
  - reduces exposure to mixers, loaders, applicators and reentry workers
- non-target organism effects (birds)
  - very low toxicity to birds
  - very low toxicity to honeybees
  - significantly less toxicity/risk to birds than alternatives not harmful to beneficial insects, highly selective pest impacts
- non-target organism effects (fish)
  - very low toxicity to fish
  - less toxicity/risk to fish than alternatives
  - potential toxicity/risk to fish mitigatable
  - similar toxicity to fish as alternatives but significantly less exposure
- groundwater (GW)
  - low potential for GW contamination
  - low drift, runoff potential
  - runoff mitigatable

- lower use rates than alternatives, fewer applications
- low pest resistance potential (i.e., new mode of action)
- highly compatible with IPM
- efficacy.

OPP has also assessed eleven of the sixteen reviews conducted by the Reduced Risk Committee of submissions that were determined not to be reduced-risk. Those factors that most significantly contributed to an unacceptable decision by the committee are summarized below in descending order:

- human health effects
  - inadequate/inappropriate comparisons with alternatives
  - inadequate documentation of effects
  - human health risk reduction case weak
  - risk reduction case inadequate when compared to alternatives
- non-target organism effects (birds and fish)
  - toxic to birds
  - toxic to fish
  - risk reduction case inadequate when compared to alternatives
- potential GW problems
- unlikely to displace higher risk alternatives
- lack of efficacy data
- phytotoxicity.

This survey of past decisions should assist future applicants in preparing their submissions.

VI. PROCEDURES AND GUIDELINES FOR EXPEDITED REVIEW OF CONVENTIONAL AND ANTIMICROBIAL PESTICIDES

A. Background

In general, FIFRA section 3(c)(3)(A) requires EPA after receipt of an application for registration of a pesticide "as expeditiously as possible" either to register it or to notify the applicant that the application does not comply with the Act. FIFRA also establishes expedited review procedures for a variety of Agency activities associated with the registration of pesticides, including expedited review for certain end-use pesticides that are identical or substantially similar to currently registered pesticides ("me too" registrations) as provided in FIFRA section 3(c)(3)(B)(II), and for antimicrobial pesticides as provided for in FIFRA section 3(h)(2). EPA also has several programs to expedite the registration process for biological pesticides by the Biopesticides and Pollution Prevention Division, antimicrobial pesticides by the Antimicrobial Division and fast track procedures to expedite the registration of certain amendments to existing conventional pesticide registrations. As a result of these programs, EPA is already expediting many pesticide applications for registration.

FIFRA section 3(c)(10) establishes an expedited review for applications for registration and amendments to registrations for pesticides that "may reasonably be expected to accomplish one or more of the following:

(i) Reduce the risks of pesticides to human health.

(ii) Reduce the risks of pesticides to nontarget organisms.

(iii) Reduce the potential for contamination of groundwater, surface water or other valued environmental resources.

(iv) Broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective."

The statute does not establish deadlines for review of registration applications or amendments that meet the above criteria. Section 3(c)(10), however, requires EPA to notify the applicant whether the application for expedited review is complete no later than 30 days after receipt of the application.

B. Procedures

EPA intends to establish a two-step procedure for expedited review pursuant to FIFRA section 3(c)(10).

1. Step One – Application. For step 1, the Agency will determine whether an application for registration or amended registration qualifies for expedited review based upon whether use of the pesticide proposed by the application may reasonably be expected to accomplish one or more of the criteria listed in Section VI.A. above.

To initiate the process, the applicant must submit an application for expedited review demonstrating how the use of the pesticide may reasonably be expected to accomplish one or more of the criteria listed in section VI.A. above. The applicant also must submit a reduced-risk rationale pursuant to the guidelines and procedures specified in sections VII - IX of this notice. The step 1 rationale may be a sentence or a paragraph in the reduced-risk rationale summary as long as the claims are documented elsewhere in the reduced-risk rationale.

Certain types of pesticide applications for registration and amended registration already receive expedited review pursuant to existing Agency programs. Because the Agency is already expediting review of these registrations, it is not necessary to include them in the review program established pursuant to FIFRA section

3(c)(10). Applications that already receive expedited review include applications for registration or amended registration for biological or antimicrobial pesticides, "me-too" applications for registration or amended registrations of end-use pesticides under FIFRA section 3(c)(3)(B)(I) that are identical or substantially similar to other EPA registered pesticide products, and applications for certain pesticides under FIFRA section 3(c)(3)(B)(II).

The FQPA amendments require EPA to make expedited decisions on antimicrobial pesticides as defined in FIFRA section 2(mm). Specifically, FIFRA section 3(h)(2) establishes goals for the time periods during which EPA must review different types of applications for antimicrobials covered by the statutory definition and make decisions whether to approve or deny the applications. Generally, these review and decision deadlines are 30% to 60% shorter than historic Agency performance in processing such applications.

While FIFRA antimicrobial review deadlines do not become legally binding until May 1998, as a matter of policy, the Agency has committed to and, in fact, is meeting the goals specified in FIFRA section 3(h)(2) as well as the expedited deadlines already mandated in FIFRA section 3(c)(3)(B). For every application received by the Agency since November 1, 1996, the Agency has made a registration decision within the review periods provided by the statute. EPA will continue to expedite review of applications for registrations and amendments to registrations for antimicrobial pesticides pursuant to its commitment.

The Agency's improved performance in review of antimicrobials is the result of several new initiatives. First, EPA has established within the Office of Pesticide Programs a new Antimicrobials Division (AD) that is responsible for all regulatory decisions relating to antimicrobial and related pesticides. In addition to regulatory staff, the new AD organization includes

scientific personnel capable of performing most of the analyses needed to make a registration decision. Thus, AD is capable of providing "one-stop shopping" for registration decisions. Second, the new AD management team has instituted a number of process improvements, including a dedicated expedited review team of "me-too" applications, that have resulted in a significantly improved performance.

Thus, because EPA's current organizational and resource allocations, and process improvements are providing expedited review for antimicrobials, all types of applications for antimicrobial pesticides (as defined in FQPA) will be outside the scope of this PR Notice.

What types of applications for expedited review will the Agency accept? An application for expedited review may be submitted only for the following types of actions:

(a) an application to register a conventional pesticide that contains an active ingredient not contained in any currently registered pesticide, provided the pesticide is not a biopesticide or an antimicrobial pesticide (as defined in FQPA). [See sections VII through IX for reduced-risk rationale guidelines]; or

(b) an application to amend the registration of a currently registered conventional pesticide for an additional new use, provided the pesticide is not a biopesticide or an antimicrobial pesticide (as defined in FQPA). [See sections VII through IX for reduced-risk rationale guidelines]; or

a non-fast-track application for registration of a new formulation provided the pesticide is not a biopesticide or an antimicrobial pesticide (as defined in FQPA). [See section X for expedited review rationale guidelines].

2. Step 2 – Reduced-Risk Determination. If an application for expedited review qualifies under step 1, the Agency will expedite the review of the reduced-risk rationale presented by the applicant to determine whether the pesticide qualifies under the reduced-risk criteria described in sections VII and X below. The Agency's Reduced-Risk Committee will expedite the review of the reduced-risk rationale and complete its review within thirty days of receipt of a complete reduced-risk rationale. If the Agency decides that a pesticide qualifies for reduced-risk status, then it will further expedite review of the remainder of the application for registration or amended registration as described in section IV of this notice.

If the Agency denies a submission reduced-risk status, applicants will be given only one opportunity to rebut this decision, and the applicant will have four weeks to resubmit their rebuttal. Due to limited program resources, the Agency can only allow one opportunity to rebut a decision. Pesticides that EPA determines do not qualify for reduced-risk status during step 2 will be processed in accordance with existing Agency procedures.

VII. GUIDELINES FOR REDUCED RISK RATIONALES

While participation in the reduced-risk pesticides program is voluntary, those who elect to participate must fully address all of the following areas: (a) executive summary, (b) human health effects; (c) environmental fate and effects; (d) other hazards; (e) risk discussion (f) pest resistance and management (e.g., IPM); and (g) comparative performance, (h) other information and how application complies with FQPA. The Agency will consider all of these areas in determining the acceptability of these applications. However, these may not be the exclusive factors in all cases. If an applicant identifies additional criteria that substantiate the argument that their product is indeed a reduced-risk pesticide, then EPA invites the applicant to submit a rationale with any

supporting data to verify such a claim. The Agency will consider this additional information.

An applicant's documentation must contain both a discussion of the inherent reduced-risk properties of their product, as well as a comparison of those properties with the properties of the commonly-used alternatives where appropriate. Comparisons must be made to conventional chemical pesticides, antimicrobial pesticides, biological pesticides, and cultural practices currently being used for pest control at the same use site(s) and for the same pest(s).

Please note that the Agency does not expect the applicant to perform any additional testing to derive the data necessary to develop rationales for the Reduced-Risk Program. The applicant must summarize all data in the applicant's possession or control or available through the open literature for the product being submitted to the Agency. If data addressing one of the stated factors has been developed, but is not required for registration of the pesticide in the United States, the applicant must provide a summary of these data as part of the Reduced-Risk Rationale. If any of the required information is not known, that fact must be noted in the rationale.

If the rationale does not include a discussion of each of these factors or provide reasoning as to why the factor should not be considered in the Agency's decision, OPP will consider the rationale to be incomplete and not responsive to this PR Notice. However, if the applicant believes that the factor does not apply to the new pesticide, the registrant must provide a short rationale describing this reasoning.

In situations where the Agency has already reviewed data on the active ingredient, the applicant should use the Agency's review to address the relevant factor(s). Applicants must also provide Master Record Identification (MRID) numbers for each study, where appropriate.

A. Executive Summary. Provide an executive summary that addresses the following considerations:

1. Chemical Name.
2. Chemical Abstracts Service Registry Number.
3. Chemical Structure.
4. Chemical Class or Family Name of the Active Ingredient.
5. Mode/Mechanism of Pesticidal Action for the Active Ingredient (if known).
6. Proposed Use Pattern (including site(s) of application and pest(s) controlled), Application Methods, Application Rates, Frequency of Application, and Product Formulation Percentages. Also indicate whether the new chemical will be used in combination with other registered pesticides.
7. Brief Overview Summary of the Health, Ecological and Environmental Fate Effects.
8. Tier 1 statement stating which of the four FQPA criteria are being met by this application.
9. Reduced-Risk Statement, articulating the specific factors that lead the applicant to the conclusion that the active ingredient offers the opportunity for risk reduction.
10. Data Matrix, providing tabular information on all data available for the active ingredient. The table should include the guideline reference number, the study title, MRID number (if available), outcome of the Agency's evaluation (i.e., in review, acceptable, supplemental, data waived, etc.),

and date of the Agency's review (if applicable).

B. Human Health. Clearly identify the portion of the rationale which addresses the potential effects of the active ingredient on human health. When specifying the dose levels used in the toxicity studies, present the no-observable-effects level (NOEL) and the lowest-observable-effects level (LOEL). Doses need to be specified in terms of mg/kg/day. Also, describe qualitatively and quantitatively the array of effects at all dose levels tested. In the format described in Part IX of this PR Notice, address each of the following aspects of the active ingredient and its use:

1. Acute Toxicity of the active ingredient and the formulations. Provide the toxicity category for each of the acute toxicity studies conducted on the active ingredient and the formulated products.
2. Reproductive, Developmental, Mutagenic and Neurotoxic Properties of the active ingredient.
3. Oncogenic and Other Subchronic and Chronic Effects of the active ingredient.
4. Toxicity of Mammalian and Plant Metabolites.

C. Environmental Fate and Effects. Clearly identify the portion of the rationale which addresses the potential ecological effects of the active ingredient and its environmental fate. The discussion should also address potential environmental degradates or metabolites of the active ingredient. Address each of the following aspects of the active ingredients and its use:

1. Mammalian Acute Toxicity
2. Avian Acute and Subacute Toxicity
3. Avian Reproductive Toxicity

4. Fish Acute and Chronic Toxicity
5. Aquatic Invertebrate Toxicity
6. Honeybee Acute Contact Toxicity
7. Effects on Terrestrial Plant Growth
8. Effects on Aquatic Plant Growth
9. Potential Exposure to Non-target Organisms
10. Environmental Persistence (Soil and Water)
11. Mobility in Soil and Water
12. Transport in Air (Spray Drift and Volatility)
13. Bioaccumulation as Indicated by the Octanol/Water Partition Coefficient

D. Other Hazards. Clearly identify the portion of the rationale which addresses other potential human health and environmental hazards produced by the following:

1. Potential to Deplete Stratospheric Ozone thus increasing ultraviolet radiation.
2. Potential to Present a Hazard through Storage, Transportation, Mixing, Use or Disposal based on its physical or chemical characteristics:
   a. stability
   b. flammability
   c. corrosion characteristics
   d. explodability
   e. oxidizing or reducing action
   f. storage stability
3. Potential to Affect Endangered and/or Threatened Plant and Animal Species as designated under the Endangered Species Act.

E. Risk Discussion. Clearly identify the portion of the rationale which addresses the following items:

1. Discuss the information which supports the claims that the active ingredient presents reduced toxicity, reduced exposure to humans or non-target organisms, and/or reduced environmental burden. When discussing the ecological levels of concern (LOCs), present the methods used to derive them and provide interpretations of what the LOCs mean.
2. Where alternative, registered pesticides or pest control practices exist, make a quantitative and/or qualitative comparison between the risks posed by the active ingredient under consideration and all the other pesticides commonly used, and/or the other current pest control practices.
3. The comparisons with alternative technology should also include biological pesticides as well as cultural and mechanical pest management practices.

F. Pest Resistance and Management. Clearly identify the portion of the rationale which addresses the following items:

1. Describe how the active ingredient addresses the development of pest resistance, either to the active ingredient itself or to existing pesticides registered for the same use.
2. Discuss the suitability of the active ingredient for use in, or encouraging the adoption of, Integrated Pest Management (IPM) programs. This discussion should include information on the effects of the

pesticide on natural predators, parasites and pathogens of each target pest, if such information is known. The degree of risk and/or usage reduction to be achieved by the IPM program must also be addressed.

G. Comparative Performance Data (efficacy data). These data are important to assure that risk reduction has a reasonable opportunity to be accomplished by adoption of the new pesticide by growers.

1. It is desirable to have summaries of comparative performance data in which the performance of the candidate pesticide is compared to that of alternative control measures under actual-use or simulated actual-use conditions.

2. Summaries of the available efficacy data if comparative performance data are not available.

Summaries should include statistical analysis of significant differences between the new pesticide and the commonly used alternatives. Summaries should also include experimental methodologies such as application rates, application intervals, pest pressure, weather conditions, varieties of the crop used, etc. Unfavorable results must be included. Efficacy experiments performed under substantially different conditions should not be combined (examples include differences in pest pressure, geography, strain/race of pest and weather). Guidance for this requirement can be obtained from standardized published tests such "Fungicide and Nematicide Tests," "Insecticide and Acaricide Tests" and methods section sections of juried professional journals.

H. Other Information. Submission of the following additional information will assist the Agency in making its decision on the active ingredient:

1. A copy of the proposed product label(s).

The Agency will consider all of these criteria using a weight-of-evidence approach.

VIII. GUIDELINES FOR FQPA RATIONALE FOR REDUCED RISK PESTICIDES

Reduced-risk submissions should also provide a rationale that explains how this registration action complies with the requirements of FQPA. Such rationale should follow guidance provided in Appendix A of PR Notice 97-1 (January 31, 1997). Such rationale should address at a minimum aggregate risk, special sensitivities, endocrine effects and potential common mechanisms of toxicity with other registered pesticides. Appendix A is provided as an attachment to this notice.

IX. FORMATTING AND SUBMITTAL PROCEDURES FOR REDUCED-RISK PESTICIDES

Formatting (A) and submittal (B) procedures for Reduced-Risk Rationales are provided below. These procedures will enable EPA to easily identify the application for priority consideration. Also, applicants should note that it is unlawful to falsify any portion of an application. FIFRA Sections 12(a) (2)(M), 12(a)(2)(R) and 18 U.S.C. Section 1001 make such actions unlawful and can result in civil or criminal penalties. The Agency will not consider an application under the Voluntary Reduced-Risk Pesticide Initiative if the applicant does not follow these procedures.

A. Format. The reduced-risk rationale document must include the following elements in the order indicated: Title Page, Statement or Supplemental Statement of Data Confidentiality Claims, Cover Sheet to Confidential Attachment and Confidential Business Information (CBI) Reduced-Risk Attachment. Any supporting data must comply with PR Notice 86-5 requirements.

The Reduced-Risk Rationale must be bound as a separate entity and consecutively paginated beginning with the title page as page 1. The total number of pages must be represented on the title page. Do not include CBI on the title page. On the title page, include titles and author(s).

B. Submitting a Reduced-Risk Rationale Registration Application. The Reduced-Risk Rationale should accompany the registration application and supporting data packages. This PR Notice does not supersede established submittal procedures as addressed in PR Notice 91-5; rather, this PR Notice provides additional guidance for submitting the reduced-risk rationale. OPP uses distribution codes to facilitate the delivery of registration and other submissions within the program. When preparing your submission to mail or deliver to OPP, direct your submission to the Document Processing Desk and including the following distribution code: REDUCED-RISK APPL.

The submission delivered via the U.S. Postal Service should be directed to OPP using the following address:

Document Processing Desk (REDUCED-RISK APPL.)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

Submissions via personal or courier delivery should be directed to the Document Processing Desk between the hours of 8:00 a.m. and 4:00 p.m., Monday through Friday, excluding federal holidays. OPP's Document Processing Desk is located at the following address:

Ofice of Pesticide Programs
Document Processing Desk (REDUCED-RISK APPL.)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

C. Rebuttals may be submitted to Rick Keigwin, Registration Division (7505C), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.

X. GUIDELINES FOR EXPEDITED REVIEW OF NON-FAST-TRACK NEW FORMULATIONS FOR CURRENTLY REGISTERED CONVENTIONAL PESTICIDES

Some new, non-fast-track, formulations and amendments to currently registered conventional pesticide products could result in reduced risk. To qualify, an application for expedited review under this section must first demonstrate that it meets one or more of the step 1 criteria listed in section VI.A of this notice. Secondly, the registrant must demonstrate that the new formulation, when compared with all of the existing formulation(s) for the active ingredient, results in significant risk reduction. Examples of risk reduction that would most likely qualify for expedited review include new formulations that result in (a) at least a 35% reduction in the amount of active ingredient applied, (b) at least a ten fold reduction in risks to mixers, loaders and applicators, (c) at least a 50% reduction in the product's potential to leach into groundwater or run off into surface water or (d) a significant reduction in risk to non-target species. Actions that are accepted will qualify for expedited review but will not be classified as reduced risk.

The process for submission of a non-fast-track formulation or new end-use product differs from the new active ingredient/new uses procedures. For consideration of a non-fast-track new formulation/end-use product, the registrant shall make a submission to the Product Manager with documented rationale for consideration of expedited review. The Product Manager will review the request and determine if the submission qualifies for expedited review. Consultation with other Product Managers or Branch Chiefs in Registration Division may

be necessary. The Product Manager will notify the applicant of the expedited review status within 30 days. If denied expedited review status, there will be one opportunity for rebuttal; the submitter has four weeks to resubmit their rebuttal to the PM. Finally, if the applicant holds the registrations for the old formulations that this new formulation will replace, a request for cancellation of the old formulations is also required. This cancellation request will not be processed until a registration is issued on the new formulation.

XI. BIOLOGICAL PESTICIDES

A. Background. In November, 1994, EPA established a pilot division, the Biopesticides and Pollution Prevention Division (BPPD), with part of its mission to expedite the registration and reregistration of biological pesticides (biopesticides). Biopesticides are any of the following: (1) naturally occurring or genetically altered microorganisms, (2) plant-pesticides (pesticidal substances produced in a plant and the genetic material necessary for the production of those substances), or (3) biochemical pesticides. In addition, BPPD does review the registration submissions for some other pesticidal substances which warrant a reduced data set as described below in Part C.

BPPD is now a permanent part of the Office of Pesticide Programs. To date, BPPD has been successful at expediting the registration of biological pesticides. Since the Division was established in the fall of 1994, 37 new biological pesticides have been registered including the first plant-pesticide products. New biopesticide active ingredients are typically registered in less than 11 months which is substantially less time than the average review time for conventional pesticides.

B. Priority for Review in BPPD. EPA believes that biological pesticides generally pose less risk than most conventional pesticides. Therefore, EPA established

BPPD to provide an expedited review to all biological pesticide products. BPPD's priority of actions is based upon the order submissions are received rather than a comparison of risk among the biopesticides. When a particular pesticide registrant requests that a certain one of its submissions receives top priority amongst that company's other biological actions, BPPD honors the requests. Also, if a biopesticide would replace the use of a hazardous pesticide requested for an emergency exemption under FIFRA Section 18, BPPD would make a case-by-case determination on whether to further expedite the regulatory decision.

C. Characteristics of Biopesticides

1. Microbial Pesticides. Microbial pesticides contain a bacterium, fungus, virus, protozoan or alga as the active ingredient. Approximately 50 microbial pesticide active ingredients are registered by EPA. The most widely known of these are varieties of the bacterium, Bacillus thuringensis or Bt, which can control certain moths, beetles, and mosquitoes. Data requirements for microbial pesticides are found in 40 CFR 158.740. BPPD encourages potential registrants to contact the Division for a preregistration submission meeting to discuss these data requirements, and the scientific rationales for study waivers.

2. Plant-Pesticides. In November of 1994, EPA published a proposed rule for regulation of plant-pesticides. In that document, EPA encouraged potential registrants to follow the proposed rule until the final rule is published. To date, seven plant-pesticide registrations have been issued. Once the final rule is published, EPA will propose guidelines for registration of plant-pesticides which will be incorporated into 40 CFR Part 158. The guidelines will be open to public comments and appropriate public meetings will be held prior to final guidelines being issued. In the meantime, potential

registrants should work closely with BPPD to determine the data requirements for their products.

3. Biochemical Pesticides. Biochemical pesticides are distinguished from conventional chemical pesticides by their nontoxic mode of action toward target organisms (usually species specific), e.g. growth regulation or mating disruption, and by the natural occurrence of the pesticidal substance. In contrast, conventional pesticides generally are toxic and may affect a wider range of target species. Biochemical pesticides generally fall into distinct biologically functional classes: Semiochemicals (chemicals emitted by a plant or animal that modify the behavior of receptor organisms of similar or different species), hormones, natural plant regulators, natural insect growth regulators, and enzymes. In many instances, biochemical pesticides may be synthesized rather than isolated from nature. In order for synthesized pesticides to be considered as biochemical pesticides, they must be demonstrated to be structurally similar and functionally identical to a naturally occurring biochemical pesticide.

Although there are no strict criteria for the definition of biochemical pesticides, most biochemical pesticides are applied at very low rates, are highly volatile, or are applied in bait, trap, or "encapsulated" formulations, thus resulting in less exposure (and less likelihood of adverse effects to humans and the environment than from use of most conventional pesticides). In keeping with their unique properties, biochemical pesticides have been assigned a set of data requirements which are organized in a tiered testing scheme to ensure, to the greatest extent possible, that only the minimum data sufficient to make scientifically sound regulatory decisions will be required. The data requirements are outlined in 40 CFR Part 158.690.

4. Pesticides Which Warrant Reduced Data Requirements. The Agency recognizes that many naturally occurring pesticidal chemicals may be highly

toxic to their target organisms and does not intend to include these as biochemical pesticides. BPPD has elected to review certain of these naturally occurring pesticides that may operate via a toxic mode of action toward target organisms, but which a priori also would be candidates for an initial tiered data set, as required for biochemical pesticides. These "biochemical-like" pesticides have not yet been formally classified into a subcategory of pesticides for nomenclature purposes. These pesticides usually have uncomplicated structures and are commonly present in the environment or the human diet at significant levels or have been widely used for non-pesticidal purposes. Thus, any clinical or nontarget effects are very likely to have been noticed and should be well documented. BPPD has found that potential registrants for these products generally follow the same data requirements as the biochemicals, but a preregistration meeting with the Division is highly recommended before extensive testing and before formal submission of an application.

D. Guidelines for Classification as a Biochemical or a "Biochemical-like" Pesticide to be Reviewed by BPPD. On request, the Biopesticides and Pollution Prevention Division (BPPD) will evaluate products on an individual basis to classify them as biochemical pesticides, pesticides warranting reduced data requirements ("biochemical-like"), or conventional chemical pesticides.

BPPD has formed a Biochemical Classification Committee to evaluate written requests for classifying products proposed for BPPD review as biochemicals and similar products. A classification request should include information to support the natural occurrence of the chemical and information bearing on its mode of action toward the target pest. Additional information to support low toxicity or low exposure levels may be useful if available. This could include GRAS (generally regarded as safe) status (please cite the listing number) or information on application rates and/or degradation rates. Published

studies or private data should be attached if the supporting information is not commonly known or obvious.

E. Evaluation Standards

1. Natural Occurrence. Naturally occurring substances may be inorganic or organic. As noted above, if the chemical is not naturally occurring, information must be provided showing that it is structurally similar and functionally identical to a naturally occurring substance. The Biochemical Classification Committee recognizes that "natural occurrence" may technically include substances that occur at very low levels in the environment, but in such amounts or locations that humans and/or nontarget organisms have not been exposed to significant levels of these chemicals. The committee may decide that these substances are not biochemical pesticides if there is any indication that natural exposure levels are insufficient to indicate potential effects from the expected product exposure.

2. Nontoxic Mode of Action. A nontoxic mode of action is one that does not kill the target pest. The most obvious are repellents and attractants. The committee has also included in the nontoxic mode of action category, those chemicals that may be lethal to the target, but operate via a physical mode of action to control the target pest. For example, certain oils and/or sticky substances can kill insects by clogging their respiratory spiracles and trachea, but such substances are not likely to have adverse effects on non-target organisms or humans. Desiccants also are considered as acting via a nontoxic mode of action. Plant growth regulators are usually considered to have a nontoxic mode of action; however, some plant growth regulators may act as herbicides at higher application rates. Thus, higher application rates may result in additional data requirements (as required for conventional chemical herbicides) or reclassification as a conventional chemical pesticide.

F. Formatting and Submittal of Request for Biochemical Classification. The classification request should be in the form of a letter and should be sent directly to the Biopesticides and Pollution Prevention Division (7511W), Office of Pesticide Programs, US Environmental Protection Agency, 401 M St SW, Washington, DC 20460. It should be labeled "Attn.: Biochemical Classification Committee."

G. EPA Response to Request for Biochemical Classification. Submissions for classification are reviewed by a team of scientists from several divisions within OPP. The recommendations of the Committee are brought to management for approval. Decisions can include classification as a biochemical, classification as a "biochemical-like" substance that warrants reduced data requirements, but is not a biochemical, or classification as a conventional pesticide. The potential registrant is informed by letter of the decision. Because these are preapplication requests for classification, the information submitted and the results may, upon request, be treated as confidential business information.

H. Rebuttals to Denials for Biochemical Classification. In some cases, inadequate information is supplied so that a Committee recommendation cannot be made. In these cases the potential registrant is asked to submit additional information. If a potential registrant disagrees with classification as a conventional pesticide (essentially a denial of classification as a biochemical), a rebuttal can be submitted to the Biochemical Classification Committee for reconsideration.

XII. FOR FURTHER INFORMATION

For further information on reduced-risk submissions for conventional pesticides, contact Peter Caulkins, Associate Director, Registration Division at (703) 305-6550. For further information on antimicrobial pesticides, contact Bill Jordan, Associate Director, Antimicrobials Division at (703) 308-6411. For further information on microbial and plant-pesticides, contact Phil Hutton, Chief, Microbial Pesticides Branch, BPPD at (703) 308-8260 and for biochemicals, contact Roy Sjoblad, Chief, Biochemical Pesticides Branch, BPPD at (703) 308-8269.

Daniel M. Barolo, Director
Office of Pesticide Programs

APPENDIX A

CONTENT OF SUPPLEMENTAL INFORMATION

As indicated at the beginning of the PR Notice, registrants, applicants and petitioners are not currently required to submit any additional information. Nevertheless, since the new statute requires the Agency to consider additional information in order to make the necessary decisions, EPA recognizes that many registrants, applicants and petitioners may wish to provide the supplemental information to the Agency even without a requirement to do so. For those registrants, applicants or petitioners who wish to supplement their original submissions with additional information, this Appendix describes what information the Agency would consider helpful additions for its review.(*1)

(*1) An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it either displays a currently valid OMB control number or is imposed on the person by statute (5 CFR 1320.6(a) & (e)). The collection of information relating to the registration, reregistration, and tolerance programs have are approved under OMB Control Numbers 2070-0024 (expires: 6/30/99); 2070-0032 (expires: 5/3/98); 2070-0040 (expires: 11/30/99); 2070-0060 (expires: 5/31/98); 2070-0122 (expires: 11/30/97); 2070-0107 (expires: 7/31/99). If you should have any comments on the collection activities, please send them to the Director, OPPE Regulatory Information Division, U.S. Environmental Protection Agency (Mailcode 2137), 401 M St., S.W., Washington, D.C. 20460. Include the OMB control number in any correspondence. Note that this address is ONLY for comments on the collection activity. Do not submit your information to this address.

All tolerances or tolerance exemptions and associated registration actions under FIFRA section 3 or reregistration actions under FIFRA section 4, whether pending or future, will need to comply with the new safety standard of section 408(b)(2) of the Federal Food, Drug and Cosmetic Act. In addition, because EPA intends to apply a similar standard to actions involving non-food use pesticides that may pose significant non-dietary risks to infants and children, all registration and reregistration actions also will need to comply with this standard with respect to the Agency's consideration of infants and children exposure to the pesticide.

In preparing a package to be submitted, those seeking a registration, reregistration, tolerance, or an exemption from the requirement of a tolerance for a food use pesticide, or a registration or reregistration of a non-food use pesticide that may result in significant exposure to children, may need to provide additional information and/or materials to address adequately the factors and specific questions contained here. Those who wish to submit additional information should keep in mind that the Agency will consider each factor listed below (and perhaps others as Agency policies are developed) in addition to any data and information already required. In addition, it is important to note that the information identified here may not be definitive in all cases. Additional information or more detailed information may be needed in individual cases. If a registrant, applicant, or petitioner can identify additional information that would assist the Agency in addressing the FQPA provisions, EPA welcomes such information. Although the submission of this information is not currently required by the regulations, if such information is not submitted, the Agency must rely on previously submitted data, if applicable, or on broad or default assumptions when considering the factors listed. As a result, favorable action on an application, petition, or reregistration decision may be significantly delayed or precluded altogether.

It would be helpful for any submitted documentation to contain a discussion of each of the following factors as it relates to the pesticide and proposed tolerance or tolerance exemption. If information on any factor is not known, that fact, along with an explanation, should be noted in the rationale. It is important to note that EPA does not expect the registrant, applicant, or petitioner at this time to perform any additional testing to derive the data necessary to develop its rationales. However, if it has in its possession data from preliminary reports of ongoing studies, articles from published literature, unpublished report information, previously unsubmitted studies, or supplemental data that are otherwise pertinent to the Agency's concerns, the party is encouraged to submit them. Likewise, if a registrant, applicant, or petitioner believes that a factor is not applicable to its product, a discussion as to why this view is held should also be included. The Agency will consider all relevant factors in determining an application's completeness and in setting priorities for review.

Based on the new safety standard, EPA will need the following additional information in order to make appropriate regulatory decisions: (For details on each factor, please refer to the explanations below in parts A and B.)

1. An informative summary of the petition or application, including a summary of the supporting data, information, accompanying rationales, and a statement providing permission to publish such summary, and
2. Information and discussion pertaining to a specific safety determination for infants and children including their special susceptibilities and exposure patterns to the particular pesticide.

A. Food Use Pesticides: Registration and Reregistration Actions, Experimental Use Permits, Tolerance (or Exemption) Petitions and Reassessments

In the format described in Appendix C of this PR Notice, address each of the following with respect to the pesticide and its use(s):

Special Sensitivities

a) Chronic Endpoints

For a chemical pesticide: Discuss and/or provide evidence as to whether or not the current Reference Dose (RfD) is sufficient to adequately protect infants and children. Discuss and/or provide evidence as to whether or not infants and children are more susceptible to the chemical. If you believe that an additional safety factor of 10X, to take into account potential pre- and post-natal toxicity to infants and children is not necessary, provide evidence to support the additional safety factor, if any, you believe to be more appropriate. Please bear in mind that the Agency may accept a different margin of safety only if, based on reliable data, EPA concludes that the margin will be safe for infants and children.

For a biochemical pesticide:(*2)

(*2) A biochemical is a naturally-occurring compound, or substantially similar to a naturally-occurring compound, with a non-toxic mode of action to the target pest.

Does the toxicity testing indicate that the establishment of an RfD is warranted? If so, then discuss whether or not the RfD is sufficient to adequately protect infants and children. Discuss and/or provide evidence as to whether or not infants

and children are more susceptible to the biochemical pesticide.

For a microbial pesticide:(*3)

(*3) Certain subpopulations are more susceptible to certain disease-causing microorganisms; however, these are not the types of microorganisms that are considered for registration or use as microbial pesticides. The Agency has not registered, and does not expect to register a microbial active ingredient that is known to be a common human pathogen. To address the potential risk from microbial pesticides, the Agency requires a battery of acute toxicity/pathogenicity studies in order to perform a risk assessment. If results of the acute exposure studies indicate a toxicity concern, then subchronic or chronic studies are required.

Discuss the potential for chronic dietary risks for infants and children. Discuss and/or provide evidence as to whether or not infants and children are more susceptible to the microbial pesticide than is the adult population.

b) Acute Endpoints

Discuss the potential for greater acute dietary risk for infants and children. If the chemical or biochemical pesticide demonstrates acute effects, then discuss the endpoint used to perform the assessment including relevance to infants and children and the details as to how the exposure assessment was conducted and whether the estimated risk is within the Agency's levels of concern.

c) Carcinogenic Endpoints

If the chemical or biochemical has been determined to be a carcinogen and has a cancer potency factor (Q1*), discuss the aggregate excess lifetime cancer risk resulting from exposure to the chemical from residues

in food and drinking water (ground and surface water) and from residential and other non-occupational source(s).

Aggregate Exposure

a) Water

For a chemical or biochemical pesticide: Discuss the potential for the transfer of residues (of both the parent pesticide and any degradates) to drinking water. The discussion should include, but not be limited to, information indicating whether the pesticide is persistent and/or mobile, relevant product chemistry, and any available modeling data.

Has the chemical or any of its degradates been detected in ground water or surface water? Would this chemical or any of its degradates likely pass through primary or secondary drinking water treatment into finished water? Are any States conducting water monitoring programs for this pesticide? If so, data collected by the States and all relevant information should also be included.

For a microbial pesticide: Discuss the potential for the transfer of the microbial pesticide to drinking water. The discussion should include, but not be limited to, information pertaining to the biology of the microorganism, and indicating whether the pesticide is persistent and/or mobile or has the potential for transport in air (spray drift and volatility data). Are any States conducting water monitoring programs for this strain? If so, data collected by the States and all other relevant information should also be included.

b) Non-occupational Exposures

Discuss the potential for significant exposure to the pesticide of children by routes other than dietary. Are there any non-occupational, structural, or residential uses (e.g., pet, swimming pool, lawn and

garden, or topical insect repellent)? Is the pesticide used in or around schools, parks, or recreation facilities? Provide all available exposure data. If the pesticide demonstrates acute effects, then discuss the endpoint used to perform the assessment, including relevance to infants and children and the details of how the residential exposure assessment was conducted and whether the estimated risk is within the Agency's levels of concern.

c) Multiple Pathway Assessment

Discuss the chronic and/or acute risk of aggregate exposure via multiple pathways for the general population, and for infants and children. This should include a discussion of all assumptions used and uncertainties. You should also identify, and include in the discussion, any non-pesticidal uses of the chemical (e.g., industrial, pharmaceutical, cosmetic, food additive).

Cumulative Effects

Discuss the mechanism and mode of action of this pesticide. Identify other chemicals that may fall into this category (both pesticide and non-pesticide chemicals). Provide information regarding common mechanisms and modes of action with other chemical substances based on structural similarity, same or similar endpoints, and other relevant criteria. Provide any data and/or evidence illustrating similarities at the cellular/molecular level.

Discuss the appropriateness of combining exposures in this particular case. Where data are not available, discuss appropriateness of using default assumptions and what defaults should be used.

Endocrine Effects(*4)

(*4) As indicated in section 408(p)(1) & (2), the Agency has 2 years to develop a screening method, with a total of 3 years to implement such a program.

Discuss and provide any evidence relevant to the possibility that the pesticide may have endocrine disrupter effects individually or in combination with another chemical. Include the potential for synergistic effects of your chemical in combination with other chemicals.

Identify any instances of reported (proven or alleged) adverse reproductive or developmental effects to domestic animals or wildlife as a result of exposure to your chemical, or that occurred in an area where the chemical is known to have been used. Provide all information regarding the circumstances, estimated level of exposure, and details of the effect.

Residue Chemistry

Information should include a discussion of compatibility with established Codex Alimentarius Commission Maximum Residue Levels (MRLs), submission of a practical analytical method with an appropriate limit of detection, and a discussion of the potential need for tolerances for processed foods. For tolerance exemption petitions, indicate if the chemical is on the Food and Drug Administration's Generally Recognized As Safe (GRAS) list. A summary of all tolerances and exemptions from tolerance being proposed should also be included.

Benefits Information (For Reregistration Actions Only)

If the information and data submitted indicate that an existing tolerance, reviewed according to the requirements of the new legislation, should be determined to be unsafe (that is, to exceed the "reasonable certainty of

no harm" standard), the new law allows EPA to consider pesticide benefits information in certain instances. An "eligible pesticide chemical residue" (for which an "eligible tolerance" may be applicable) is defined as a chemical residue for which

1) EPA is unable to identify a level of exposure that will not cause or contribute to a known or anticipated harm to human health (that is, the effect is a non-threshold effect);

2) an appropriate quantitative risk assessment for the lifetime risk of the non-threshold effect has been determined; and

3) if there are also threshold effects associated with the chemical, EPA is able to identify a level at which the residue will not cause any known or anticipated harm to human health and that the level of aggregate exposure is safe.

Registrants who suspect that an existing tolerance for their chemical, which has been classified by the Agency as exhibiting a non-threshold effect, may exceed the new safety standard, and wish the Agency to consider an eligible tolerance for residues of that pesticide, may need to submit the following information:

Conditions Regarding the Use of the Pesticide

Information and/or data indicating that the use of the pesticide chemical that produces the residue protects consumers from adverse health effects that would pose a greater risk than the dietary risk from the residue, OR

Information and/or data showing that the use of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in the domestic production of an adequate, wholesome, and economic food supply.

Conditions Regarding the Risk of a Pesticide

Evidence that the yearly risk associated with the nonthreshold effect from aggregate exposure to the residue is not greater than ten times the yearly risk allowed under the new safety standard, AND

Evidence that the tolerance is limited to ensure that the lifetime risk associated with the nonthreshold effect from aggregate exposure to the residue is not greater than twice the lifetime risk allowed under the new safety standard.

It is important to note that the above information does not supersede any existing benefits requirements under FIFRA, such as public health pests and benefits data necessary for a public interest finding under FIFRA section (3)(c)(7).

B. Non-Food Use Pesticides: Registration or Reregistration Actions

In the format described in Appendix C of this PR Notice, address each of the following with respect to the pesticide and its use(s):

Potential for Exposure to Children

Describe the use pattern of your chemical. If you believe that its use(s) would not potentially result in significant exposure to infants and children, provide a discussion and rationale as to why this view is held. For chemicals that appear not to result in a significant exposure to infants and children, no additional information is needed.

If you believe that the use of your chemical may result in significant children's exposure, the following factors may need to be addressed:

Special Sensitivities

Discuss and/or provide evidence as to whether or not infants and children are more susceptible to the chemical than adults.

Discuss the potential for greater acute and/or chronic risk for infants and children. If the pesticide demonstrates toxic effects, then discuss the endpoint used to perform the assessment including relevance to infants and children and the details as to how the exposure assessment was conducted and whether the estimated risk is within the Agency's levels of concern.

Aggregate Exposure

Discuss the potential for the transfer of residues of both the parent chemical and any degradates or of the microbial pesticide to drinking water. For chemical pesticides, the discussion should include, but not be limited to, information indicating whether the pesticide is persistent and/or mobile, the potential for transport in air (spray drift and volatility data), and any available modeling data. For microbial pesticides, the discussion should instead include information pertaining to the biology of the microorganism and indicate whether the pesticide is persistent and/or mobile.

Has the chemical or any of its degradates been detected in ground water or surface water? Would this chemical or any of its degradates likely pass through primary or secondary drinking water treatment into finished water? Are any States conducting water monitoring programs for this pesticide? If so, data collected by the States and all relevant information should also be included.

Discuss the potential for significant exposure to the chemical of children by non-dietary routes. Are there

non-occupational, structural, or residential uses (e.g., pet, swimming pool, lawn and garden, or topical insect repellents)? Is the pesticide used in or around schools, parks, or recreation facilities? Provide all available exposure data.

Discuss the chronic and/or acute risk of aggregate exposure via multiple pathways for the general population, infants and children should include a discussion of all assumptions used and uncertainties.

Identify other non-pesticidal uses of the chemical (e.g., industrial, pharmaceutical, cosmetic, food additive).

Cumulative Effects

Discuss the mechanism and mode of action of this pesticide. Identify other chemicals that may fall into this category (both pesticide and non-pesticide chemicals). Provide information regarding common mechanisms and modes of action with other chemical substances based on structural similarity, same or similar endpoints, and other relevant criteria. Provide any data and/or evidence illustrating similarities at the cellular/molecular level.

Discuss the appropriateness of combining exposures in this particular case. Where data are not available, discuss appropriateness of using default assumptions and what defaults should be used.

Endocrine Effects

Discuss and provide any evidence relevant to the possibility that the chemical may have endocrine disrupter effects individually or in combination with another chemical. Include the potential for synergistic effects of your chemical in combination with other chemicals and whether or not your chemical could act as a catalyst for another hormone-disrupting chemical.

Identify any instances of reported (proven or otherwise) adverse reproductive or developmental effects to domestic animals or wildlife as a result of exposure to your chemical, or that occurred in an area where the chemical is known to has been used. Provide all information regarding the circumstances, estimated level of exposure, and details of the effect.

Supreme Court, U.S.
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No. 03-388

IN THE
Supreme Court of the United States

DENNIS BATES, ET AL.,
Petitioners,
v.
DOW AGROSCIENCES LLC,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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September 13, 2004

QUESTION PRESENTED

Which, if any, state-law crop damage claims are preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 *et seq.*

PARTIES TO THE PROCEEDING

Plaintiff-Appellee in the proceedings below was Dow AgroSciences LLC.

Defendants-Appellants in the proceedings below were Dennis Bates; Jimmy Burson; Benny Judah d/b/a Clearwater Farms; Tommy Coleman; Richard Cox; Wayne Davis; Neil Friessen; Jake Forese; Thomas Fuston; Arthur Galvan d/b/a G-5 Partnership; Greg Hughes; Sandra and Karl Don Hughes d/b/a JH Cattle Co.; Rudy Klassen; Ronnie Love; Kevin Mathis; Brad Palmer; Kirk Parrish d/b/a K-L Farms; Jerry Parrish; Joevelyn Patterson; Donald Gruben; Stacey Price; Benny Judah d/b/a Progressive Farms; Morris Rushing d/b/a Pea-Cot Farms; Billy Shannon; Floyd Stokes; Craig West; and Frenchie Lee Wheeler.

Burk Denman was a Defendant in the district court proceedings but was dismissed as an Appellant in the court of appeals proceedings.

STATEMENT PURSUANT TO RULE 29.6

None of the corporate Petitioners has a parent company, and no publicly held company owns 10% or more of the stock of any such corporate Petitioner.

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The district court's opinion (Pet. App. 21a-31a) is reported at 205 F. Supp. 2d 623. The court of appeals' opinion (Pet. App. 1a-20a) is reported at 332 F.3d 323.

JURISDICTION

The court of appeals entered judgment on June 11, 2003. The petition for a writ of certiorari was filed on September 9, 2003, and granted on June 28, 2004 (124 S. Ct. 2903). Jurisdiction rests on 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS

Relevant provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 *et seq.*, and of Title 40 of the Code of Federal Regulations are reproduced in an addendum to this brief.

STATEMENT

Petitioners are a group of Texas farmers who seek recovery under state law for the substantial crop damage caused by a pesticide, Strongarm, in the growing season immediately after the Environmental Protection Agency ("EPA") approved it. They asserted the same types of claims that have been made against pesticide manufacturers for nearly a century – strict liability in tort, breach of warranty, breach of contract, negligence, fraud, and deceptive trade practices. Those claims arose out of the respondent manufacturer's written representations on the pesticide's label, and oral representations made in face-to-face meetings with the farmers before and after they purchased and applied Strongarm to the soil. In holding all of those claims preempted, the court below gave sweeping effect to the preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136v(b). The court opined that any state-law liability that might "induce" the manufacturer to change its label was "express[ly]" preempted under § 136v(b). Pet. App. 20a.

That holding affords pesticide manufacturers *carte blanche* to determine the scope of preemption because they – and not federal regulators – decide what to put on the

label. The notion that manufacturers have the authority to preempt claims that seek to redress injuries they cause, however, is alien to this Court's approach to preemption analysis, Congress's purposes in enacting FIFRA, historical practice throughout the twentieth century, and common sense. In legislation that sought to address the potential horrors of an unregulated pesticide industry, it is unthinkable that Congress – without debate – intended to exonerate manufacturers from traditional state-law remedies for the injuries they cause from dangerous chemicals.

1. Beginning in the late nineteenth century, farmers in the United States began to use a variety of primitive chemicals to attack insect pests, such as Paris green (a concoction of copper and arsenic), calcium arsenate, nicotine sulfate, and sulfur. *See* J. Whorton, *Before Silent Spring* 20-21 (1974). Those primitive chemicals augured significant changes in the agricultural pesticide industry, which grew dramatically after World War II, when advances in chemistry occasioned by military needs led to the introduction of DDT and BHC, among others. *See, e.g., id.* at 248-50; *Report of the Secretary's Commission on Pesticides and Their Relationship to Environmental Health* 44-46 (U.S. Dep't HEW 1969) ("*HEW Report*"). The seeming euphoria over the benefits of pesticides in general, and DDT in particular, led to a 1944 Nobel Prize award to the inventor of DDT. But by the 1960s, following publication in 1962 of Rachel Carson's *Silent Spring*, a major reassessment began of pesticides, due to the human health risks and environmental hazards caused by DDT. *See generally* H. Wellford, *Sowing the Wind* (1972); F. Graham, *Since Silent Spring* (1970); R. Rudd, *Pesticides and the Living Landscape* (1964). In 1972, EPA cancelled the registration of DDT in the United States. By 2001, 92 nations (including the U.S.) had signed a treaty pledging to phase out persistent organic pollutants, including DDT. *See* Stockholm Convention on Persistent Organic Pollutants, May 22, 2001, 40 I.L.M. 532, *at* http://www.pops.int/.

Notwithstanding the disastrous experience with DDT, pesticide use on farms rose rapidly in the 1960s, from $440 million in sales in 1964 to $12 billion in 1969. *HEW Report* at 46. Some 900 active pesticidal chemicals formulated into more than 60,000 preparations were marketed by that time. *Id.* By 1976, pesticides were used on 70% of U.S farm acreage planted, up from 50% five years before. *See* George Getschow, *Farmers Using More and More Pesticides To Safeguard Investment as Well as Crops*, Wall St. J., June 14, 1976, at 24.

2. The introduction of pesticides early in the twentieth century, and the attendant problems they created, led Congress to enact the Insecticide Act of 1910. That Act was principally a labeling measure covering insecticides and fungicides, the purpose being to prohibit the manufacture or shipment of misbranded or adulterated products that move in interstate commerce. *Id.* §§ 1, 2, 36 Stat. 331. Although the Department of Agriculture ("USDA") was authorized to examine specimens, Congress did not require registration or other government approval of pesticides. *Id.* § 4, 36 Stat. 332. The 1910 Act was silent as to civil remedies for violations, providing only for criminal penalties and civil actions by the federal government. *Id.* §§ 1-2, 10, 36 Stat. 331, 334.

In 1947, Congress enacted FIFRA, which repealed the 1910 Act, *see* § 16, 61 Stat. 172. FIFRA provided that an "economic poison" – otherwise defined as a chemical pesticide – had to be registered before being marketed in interstate commerce. *Id.* § 4(a), 61 Stat. 167. "Like its 1910 predecessor, the principal thrust of the 1947 FIFRA was to protect consumers on the farm and in the orchard from ineffective products." 3 W. Rodgers, Jr., *Environmental Law: Pesticides and Toxic Substances* § 5.3, at 34 (1988).

By the end of the 1960s, however, it was clear that the existing system of federal pesticide regulation was inadequate. A House subcommittee investigation in 1969 chronicled a plethora of problems, including approvals of pesticides without compliance with federal procedures,

approvals of labels that failed to warn users of possible hazards, and actions to cancel dangerous pesticides that were substantially delayed. *See* H.R. Rep. No. 91-637 (1969); *see also* Rodgers § 5.2, at 31.

Notwithstanding enactment of the 1910 or 1947 Acts, including the requirement that pesticides be federally registered before entering interstate commerce, from the earliest uses of agricultural chemicals, farmers commonly pursued claims for compensation under common law and state statutes for injuries caused by pesticides. For example, claims against pesticide manufacturers alleged crop damage for failure to test a product before it was released into the market.[1] Indeed, state courts imposed on manufacturers a duty to test their products for safety and effectiveness "under the existing climactic and soil conditions" of each State in which they sold the product. *Ebers v. General Chem. Co.*, 17 N.W.2d 176, 181 (Mich. 1945) ("[D]efendant cannot escape liability merely by showing that it followed the recommendations of [USDA] . . . based upon field tests in States *other* than Michigan.") (emphasis added). Likewise, courts upheld farmers' crop damage claims sounding in negligence under a duty to warn theory.[2] And courts routinely recognized claims against pesticide manufacturers for personal injuries.[3]

[1] *See, e.g., Chapman Chem. Co. v. Taylor*, 222 S.W.2d 820, 827 (Ark. 1949) (manufacturer "charged with the knowledge which tests would have revealed"); *Henderson v. Cominco Am., Inc.*, 518 P.2d 873, 879, 882-83 (Idaho 1973) (recognizing claim for "failing to test the product").

[2] *See, e.g., Golden Gate Hop Ranch, Inc. v. Velsicol Chem. Corp.*, 403 P.2d 351, 355 (Wash. 1965) ("[I]f [the manufacturer] knew or should have known that the product was dangerous to hops, the appellant was negligent in not advising the respondent of the danger."); *Thompson-Hayward Chem. Co. v. Childress*, 169 So. 2d 305, 312 (Ala. 1964) (recognizing claim for "failure to give notice to or warn plaintiffs of the dangerous nature of [a herbicide]"); *Reasor-Hill Corp. v. Kennedy*, 272 S.W.2d 685, 691 (Ark. 1954) (affirming verdict for failure to warn against crop damage due to insecticide drift).

[3] *Hubbard-Hall Chem. Co. v. Silverman*, 340 F.2d 402, 404 (1st Cir. 1965) (upholding verdict on failure-to-warn claims for personal injury;

By the 1960s, the "principles of law which are deducible" from the scores of cases decided throughout the twentieth century involving claims against pesticide manufacturers and sellers led to this statement of settled law: "A duty of due, reasonable care binds [pesticide] manufacturers . . . . This duty of care includes a duty to warn of product-connected dangers, a duty on the part of the manufacturer to subject the product to reasonable tests, and a duty on the part of the seller to subject the product to reasonable inspection." R.D. Hursh, *Liability of manufacturer or seller for injury caused by animal feed or medicines, crop sprays, fertilizers, insecticides, rodenticides, and similar products*, 81 A.L.R.2d 138, 144 (1962) (footnotes omitted).

3. Congressional enactment of the Federal Environmental Pesticide Control Act of 1972 ("1972 Act") amended FIFRA in important ways. *See* § 2, 86 Stat. 973-98, codified at 7 U.S.C. §§ 136 *et seq.*[4] The 1972 Act contained a more detailed registration provision (§ 136a(c) (1976)); added criteria for approval (§ 136a(c)(5)); and imposed consequences of disapproval (§ 136a(c)(6)). 86 Stat. 979-81. Congress augmented the 1970 transfer of authority to administer pesticide registration from USDA to EPA by providing in the 1972 Act for federal authority over the sale and use of pesticides. *E.g.*, § 136j. But the Act also expressly ensured that state and local governments had broad authority to regulate or even ban the sale and use of a federally registered pesticide. § 136v(a). States have the lead in enforcing pesticide use restrictions. § 136w-1.

finding no FIFRA preemption from label registration, but noting that defendants' compliance with FIFRA labeling requirements was "some evidence that . . . they exercised reasonable care"); *Orr v. Shell Oil Co.*, 177 S.W.2d 608, 614 (Mo. 1943) (affirming verdict against insecticide manufacturer for negligently failing to warn of dangers of human contact with spray ingredients); *West Disinfecting Co. v. Plummer*, 44 App. D.C. 345, 355 (1916) (affirming damages verdict for plaintiff for burn injuries where insecticide manufacturer breached its "duty . . . to label the can containing the fluid so as to show its dangerous character").

[4] Subsequent statutory cites are to Title 7 unless otherwise noted.

As part of the registration process, the manufacturer submits health and environmental data, as well as a draft label. § 136a(c)(1)(C); 40 C.F.R. § 152.50(e). EPA has stressed that "[t]he registrant must take responsibility for quality control of the product's composition and for adequate labeling describing the product, its hazards and uses." 53 Fed. Reg. 15,952, 15,956 (1988). Unlike federal statutes governing tobacco labels, *see* 15 U.S.C. §§ 1333, 4402(a)(1), neither FIFRA nor EPA regulations dictate that any particular language must be used for pesticide labels, except with respect to certain required "signal words" designed to protect human health if the pesticide contains ingredients in three of four toxicity categories. *See* 40 C.F.R. §§ 156.60-156.78.

If a manufacturer meets FIFRA's requirements, then EPA is obliged to register the pesticide. § 136a(c)(5), (7); 40 C.F.R. §§ 152.112, 152.113. Those requirements include: "the name and address of the applicant"; "the name of the pesticide"; "a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use"; "the complete formula of the pesticide"; a request as to the product's use (*i.e.*, general or restricted); and, "if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based." § 136a(c)(1)(A)-(F). A "label" is defined as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers," or other detached written matter accompanying the pesticide, such as an instructional booklet, that serves the same purpose as a label. § 136(p)(1), (2)(A). Information required by FIFRA to be on a pesticide's label must be prominently and conspicuously placed in comparison to other labeling information that is not mandated by federal law. § 136(q)(1)(E); 40 C.F.R. § 156.10(a)(2).

Notwithstanding EPA's registration of a pesticide, a label is "misbranded" if it bears false or misleading statements, contains improper directions for use, or displays inadequate cautions or warnings. § 136(q)(1)(A), (F), (G);

see also § 136a(c)(5). Cognizant that, "[f]or liability reasons, companies often voluntarily provide additional information on the label, particularly in the area of precautionary statements," 49 Fed. Reg. 37,960, 37,971 (1984), FIFRA and EPA permit such statements if they do not violate a specific statutory or regulatory requirement, *id.*

4. Although the 1972 Act required EPA to consider data and manufacturer claims concerning the efficacy of a pesticide in determining whether "its composition is such as to warrant the proposed claims for it," § 136a(c)(5)(A) (1976), those burdens were simply too great for the agency. In 1977, EPA Administrator Douglas M. Costle testified, "we feel that far too much Agency time is currently being spent in reviewing efficacy data while shortages abound in the reregistration data validation areas. Since the registrant, the USDA, and pesticide users are generally in a better position to judge efficacy, particularly of agricultural pesticides, we are proposing that the Agency should have explicit authority to waive the efficacy data requirement when appropriate." H.R. Rep. No. 95-343, at 9 (1977). In 1978, Congress acceded to that request by amending the 1972 Act to allow the EPA to waive data requirements "pertaining to efficacy" and to establish a "presumption" in favor of waiver if a pesticide is found to be effective by a state. Federal Pesticide Act of 1978, Pub. L. No. 95-396, § 5, 92 Stat. 819, 825 (§ 136a(c)(5)). EPA then issued a general waiver of its review of label claims concerning pesticide efficacy. *See, e.g.*, 44 Fed. Reg. 27,932 (1979). "The assumption in 1978 was that market choices and user votes of confidence were a fair barometer of product workability." Rodgers § 5.3, at 51.

That assumption was confirmed explicitly in 1996, when EPA issued Pesticide Registration Notice 96-4. That notice stated that "it would be incorrect to contend that the label approval process involves an examination of the efficacy of the pesticide." JA 232. EPA noted that the agency, "with Congress' approval, stopped evaluating pesticide efficacy for routine label approvals almost two decades ago.

Further, . . . EPA's regulations do not require a review of efficacy of property damage issues for agricultural pesticides." *Id.* EPA further clarified that the statutory prohibition on "misbranding" "should not be read as reintroducing efficacy concerns into the label approval process." JA 233-34. EPA concluded by stating, "as to pesticide users this Notice is intended to clarify that EPA's approval of a pesticide label does not reflect any determination on the part of EPA that the pesticide will be efficacious or will not damage crops or cause other property damage." JA 235. That guidance – and EPA's 1979 waiver – were in effect when Strongarm was registered.

5. In the early 1990s, the corporate predecessor to respondent Dow AgroSciences LLC ("Dow") began testing and developing a new herbicide that became known as Strongarm.[5] This product was touted as a revolutionary weed control for peanut and soybean crops, because it was designed to be applied once to the soil as a "pre-emergent" prior to the planting of peanut seeds. From then until the peanuts were harvested, the farmer would not need to apply any other herbicide to control noxious weeds that compete with peanuts for important nutrients. The active ingredient in Strongarm, diclosulam, was supposed to attack the roots of "target" weeds, inhibiting their growth, without affecting the "non-target" peanut crop. JA 120. Beginning in the early 1990s, however, Dow scientists learned through field tests that the absorption rate for a herbicide similar to diclosulam was significantly hindered when the soil has a pH level above 7.0. *See* R.G. Lehmann *et al.*, *Degradation of a Sulfonamide Herbicide as a Function of Soil Sorption*, 32 Weed Research 197 (1992) (CA App. 597). Later studies by Dow scientists established that, the higher the soil pH, the less likely diclosulam was

[5] As an appeal from a summary judgment for Dow, the record facts must be construed in the light most favorable to petitioners. *See Wolston v. Reader's Digest Ass'n, Inc.*, 443 U.S. 157, 162 n.5 (1979). Because Dow's motion was based on federal preemption, "no pre-trial discovery was undertaken in this case." Dow Cert. Opp. 3.

to be absorbed in the ground and thus the higher the "effect" of the herbicide on plant life exposed to the chemical. *See* J. Zabik *et al.*, *Terrestrial Field Dissipation of Diclosulam at Four Sites in the United States*, 49 J. Agric. Food Chem. 3284 (2001) (CA App. 590); JA 124. Thus, when soil pH levels reached 7.0 or greater, the Strongarm in the soil would not be readily absorbed and would retard or injure the roots of the non-target peanut plants. JA 126.

Despite those known deficiencies, Dow widely touted the putative benefits of its new pesticide. In 1999, before EPA had registered Strongarm, the Texas Department of Agriculture was sufficiently impressed by Dow's representations that it requested a special exemption to use Strongarm on 184,000 acres, or roughly half of the State's peanut crop. *See* 64 Fed. Reg. 9152, 9152 (1999).[6]

Although EPA declined the State's request, it "conditionally registered" Strongarm on March 8, 2000. JA 63-93. Because peanuts mature on a 150-day growing cycle, seeds in west Texas must be planted on or about May 1 of each year. Dow thus had to act quickly to convey information about Strongarm so that it could be sold for the 2000 planting season. At a series of "Field Days" sponsored by Texas agricultural extension agents employed by Texas A&M University and conducted in 1999 and 2000, Dow agents orally recommended Strongarm to Texas peanut farmers. *See, e.g.*, JA 147-48, 152-53, 157-58.

Petitioners, farmers who grow their crop principally for sale as packaged peanuts at baseball games and other sporting events, decided to use Strongarm on the basis of those oral presentations. *See, e.g.*, JA 148, 153, 158. It is common in Texas agriculture for farmers to hire their local agricultural supplies outlet or custom chemical applicator to apply the pesticide for them, rather than applying the pesticide themselves. Those applicators, in turn, will mix

[6] Texas has 320,000-370,000 acres of peanut farmland and ranks second nationally in peanut production. *See* Texas Agric. Ext. Serv., *Texas Peanut Production Guide* 1 (Apr. 2001) ("*Texas Peanut Guide*").

and distribute the pesticide via methods such as sprinkler outlets that they use on the farmers' land or move from farm to farm. In this manner, the farmer contracts out the task of applying pesticides without directly purchasing the pesticide or being aware of the label's contents. In any event, the Strongarm label was in plastic sealing that could not be opened or read until after purchase. *See, e.g.*, JA 148.

Within weeks after planting their peanut seeds on or about May 1, the farmers discovered signs of herbicide damage to their crops. Plants "treated with Strongarm were not growing normally, were stunted in their growth, were yellowed and discolored and were not developing foliage." *E.g.*, JA 153, 158; *see* JA 121. At this point, the farmers had applied no chemical to their land other than Strongarm, and they had no reason to suspect that the high pH content of their soil was a factor. JA 153, 158; *see also* JA 125-26, 139, 148, 158.

When the farmers contacted Dow to complain about the effects of Strongarm on their crop and to ask what they should do, Dow officials came to inspect the fields. *See, e.g.*, JA 139, 153. Those agents were able to observe a "burning" of the farmers' crop roots and made oral representations as follows: the farmers were advised to "grow out" their crop and keep a record of their extra expenses. *See, e.g.*, JA 153, 161-62. Dow would compensate them for those costs, as well as any damages they suffered from using Strongarm. *See, e.g.*, JA 148, 162.

By June, the farmers were in a terrible bind. They had little choice at that point but to follow Dow's instructions. The Strongarm was so toxic in their soil that they could not reasonably plow up their peanut plants and plant a different crop, even if their agricultural lenders would have permitted them to do so. But they could tell from the stunted growth of their peanut plants that maturation of the crop would be significantly delayed. Adding to the farmers' difficulties was that Strongarm failed to control noxious weed infestations as promised; the farmers

incurred additional costs in applying other herbicides to combat weeds and additional water to counteract the burning effect of Strongarm.

The resultant stunting of the farmers' crops created special weather-related problems. Most of the affected farms were in west Texas, where autumnal freezing rains make it imperative to harvest the peanuts by approximately October 1 to achieve the best crop. *See Texas Peanut Guide* at 10 (noting that delays in maturation of peanuts "reduce yield and quality and increase the risk of freeze damage and late season drought to peanuts"). Peanuts grow underground and are harvested by tilling up the crops and having them dry above ground. Hot, dry weather is essential to the harvesting process. But, when the stunted plants were not ready to be harvested by October 15, the farmers faced the prospect that, even if their peanuts eventually grew properly to maturity, they would have to harvest them in the fall rainy season, and the crops would be severely damaged or ruined above ground.

In late 2000 – before any new studies could have been completed and before any petitioners had sent demand letters to Dow formally seeking compensation for Strongarm-related injuries – Dow re-registered its Strongarm label with EPA, which approved the amendments on January 30, 2001. JA 123, 181. In that re-registration, Dow altered the label in multiple, significant ways. First, Dow registered a "supplemental" label that was for "distribution and use only in the states of New Mexico, Oklahoma and Texas," JA 179, the three states whose peanut farmers had experienced crop damage from Strongarm in 2000. Second, Dow explicitly stated: "Do not apply Strongarm to soils with a pH of 7.2 or greater." JA 181. (The soil on many petitioners' lands has a pH level of that amount or higher. *See* JA 125.) Third, Dow stated on the new supplemental label that the amount of Strongarm to be applied was .3 to .45 ounces per acre, as opposed to the .45 ounces per acre directed on the label conditionally approved by EPA on March 8, 2000. *Compare* JA 179 *with*

JA 75. Fourth, whereas the original label said nothing about the need for additional applications of herbicides for weed infestations other than nutsedge, *see* JA 87, the supplemental label noted that, "[w]hen using the 0.3-oz rate, weed control results on eclipta, morningglory, nutsedge, and Virginia copperleaf may be variable. A follow up treatment with another herbicide may be necessary for full season control." JA 180. Finally, rather than applying Strongarm prior to planting, the supplemental label stated that the pesticide should be applied *after* planting. JA 176, 180. "Many of the west Texas farms reported peanut injury with preplant incorporation." JA 124.

By the time EPA had conditionally approved Dow's supplemental label for Strongarm in early 2001, the farmers had an idea of the additional expenses and damages they had suffered as a result of the disastrous experiment with Strongarm, although some farmers also discovered that the lingering effects of the Strongarm in their soil impaired their 2001 crops of wheat and cotton (rotated with peanuts for soil regeneration). JA 127. But, when they presented this information to Dow, as its agents had instructed them, Dow refused to pay for the "year 2000 production loss as they promised to do." *E.g.*, JA 139. Beginning in late September 2001, a few petitioners wrote officially to inform Dow of their damages, request payment, and advise that, if no satisfaction was forthcoming, they would file suit in state court to recover their damages. *See, e.g.*, JA 36-39. Throughout the autumn, more farmers came forward to advise Dow of the problems they had experienced and to request formally that Dow honor its promise to make whole the farmers who had been damaged by using Strongarm. *See, e.g.*, JA 33-34. Under the Texas Deceptive Trade Practices Act ("DTPA"), Tex. Bus. & Com. Code §§ 17.01 *et seq.*, the farmers were required to provide written notification to Dow before they could bring suit in state court. The DTPA provides that no suit filed within 60 days of that notification shall be effective. On December 21, 2001, before the 60 days had expired for the

vast bulk of petitioners, Dow filed suit in federal district court for a declaratory judgment that all of the farmers' claims were preempted by FIFRA. *See* JA 13-23.

6. When Dow sued for declaratory relief, the farmers brought counterclaims asserting various state-law claims, including: strict liability in tort for a defective product; fraud and fraud in the inducement arising out of Dow's knowledge that Strongarm was particularly toxic in high pH soils from prior studies and the post-application representations by Dow officials that they would compensate the farmers for any harm that occurred to their crop from permitting it to grow out; a DTPA claim for deceptive practices in connection with the statements Dow had made to the farmers after Strongarm had been applied to and damaged their crops; estoppel and waiver, on the ground that Dow's contradictory oral off-label representations precluded Dow from relying on its label; negligent misrepresentation; breach of express and implied warranty; negligence; and breach of contract. *See* JA 183-93.

The district court granted Dow's motion for summary judgment, holding nearly all of the farmers' claims preempted. Pet. App. 21a. The one exception was that FIFRA did not preempt claims based on "statements made by [Dow's] employee representatives who examined [petitioners'] fields and advised them that the peanuts would grow out of the problem and that [Dow] would pay the growers for any production loss and increased expenses." *Id.* at 28a-29a. But the court held the farmers limited to the remedies specified on the label. *Id.* at 29a-30a.

The court of appeals affirmed, holding that "FIFRA expressly preempted the farmers' state law claims." *Id.* at 9a. It rested on circuit precedents announcing a rule that "FIFRA preempts state laws that either directly or indirectly impose different labeling requirements." *Id.* at 11a & n.9 (citing *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 (5th Cir. 1994)). The court reasoned that "the farmers' claims are expressly preempted under § 136v(b) if a judgment against Dow would induce it to alter its product

label," *id.* at 15a, even as to the "off label" claims, *id.* at 16a. It held that the farmers' claims were "all preempted by FIFRA's express preemption clause." *Id.* at 20a.

SUMMARY OF ARGUMENT

I. State damages actions are not preempted by FIFRA because the word "requirements" as understood by its context in § 136v(b) encompasses only rules issued pursuant to positive law, such as statutes and regulations. Section 136v(b) is a subset of a broader non-preemptive provision in § 136v(a), which expressly upholds the authority of States to issue "regulation[s]." By referring to "Such State" in § 136v(b), Congress specifically referred back to the regulations authorized in § 136v(a).

That construction is consistent with the broad non-preemptive thrust of § 136v(a), as well as the overall structure of FIFRA. The word "requirements" appears 75 times in the statute: in every instance, the word clearly refers to a duty imposed solely by positive law and not common law. FIFRA is therefore unlike statutes using word "requirements" that this Court considered in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). The legislative history contains no indication that Congress intended to upset long-standing practices in States permitting compensatory damages suits against pesticide manufacturers that caused crop damage. To construe § 136v(b) as preempting the farmers' suits would be contrary to Congress's central aim in the 1972 Act to protect the public from dangerous chemicals. Because nothing in FIFRA affords compensation to parties injured by pesticides, state-law damages claims properly fill the void left by Congress.

II. Even if the Court were to conclude that "requirements for labeling or packaging" in § 136v(b) can encompass some state-law claims, the scope of § 136v(b) permits claims against pesticide manufacturers that challenge the efficacy of the product even where such efficacy claims are made on the label. In 1978, Congress expressly authorized EPA to waive determinations of whether a pesticide is efficacious, and for a quarter-century the agency has in fact waived such requirements. Thus, claims contesting the efficacy of a pesticide impose no "requirements for labeling or packaging in addition to or different from" FIFRA.

That is also true with respect to misbranding. It is unlawful under FIFRA for a manufacturer to label a pesticide with false information, improper instructions for use, and inadequate warnings. State-law claims that are consistent with that federal prohibition are therefore not preempted. *See Medtronic*, 518 U.S. at 495; *id.* at 513 (O'Connor, J., concurring in relevant part).

In any case, many of the farmers' specific claims – such as strict liability, negligent design, fraud, and deceptive trade practices – rest on representations by Dow having nothing to do with the Strongarm label and cannot be defended with any type of "fair warning." Those claims therefore impose no additional or different labeling requirements merely because the manufacturer makes a voluntary decision to change its label and thereby seek to avert its future liability to other purchasers. The Fifth Circuit fundamentally disregarded this Court's teaching that the proper analysis focuses on the legal duty underlying each state-law claim, and not on the open-ended inquiry into whether a damages award might somehow "induce" a manufacturer to seek a change in its label from EPA. *See Cipollone*, 505 U.S. at 523-30 (plurality op.); *Medtronic*, 518 U.S. at 492-502.

III. The farmers are entitled to sue for misrepresentations that Dow made after they used Strongarm. Dow represented that it would compensate the farmers for their damages from crop loss and expenses incurred in trying to salvage their crops. By holding that "all" of the farmers' claims are preempted, Pet. App. 20a, the Fifth Circuit's internally contradictory opinion forecloses the farmers' ability to sue for those broken promises and misrepresentations in an amount beyond the label's limitation of remedies, even though those claims do not implicate Dow's Strongarm label or any other FIFRA requirement.

ARGUMENT

I. STATE-LAW DAMAGES ACTIONS ARE NOT PREEMPTED BY FIFRA

For six decades prior to the 1972 Act, farmers routinely brought state-law actions against manufacturers for damages to their crops caused by pesticides. Nothing in the text, structure, legislative history, or purposes of that Act indicates that Congress intended to change that tradition by precluding farmers from seeking redress for the damages caused to them by pesticide manufacturers.

A. The Text Of § 136v(b) Does Not Compel Preemption Of The Farmers' Claims

As with any statute, "analysis of the scope of the preemption statute must begin with its text." *Medtronic*, 518 U.S. at 485. Although the existence of an express preemption clause does not negate the need for an analysis of implied preemption, *see Freightliner Corp. v. Myrick*, 514 U.S. 280, 288-89 (1995), analysis of the clause itself "must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent," *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993).

The preemption clause at issue here follows immediately after a provision that confers significant regulatory authority on States. Together those provisions read:

> **§ 136v. Authority of States**
>
> **(a) In General**.—A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this [Act].
>
> **(b) Uniformity**.—Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this [Act].

The theory underlying preemption is that state-law claims, such as the farmers' damages claims here, impose "requirements for labeling or packaging in addition to or different from those required under [FIFRA]." § 136v(b). But the text of § 136v(b) and § 136v(a) does not support preemption of such claims.

1. "Requirements" in § 136v(b) is a subset of "regulation[s]" in § 136v(a)

The word "requirements" in § 136v(b) is used as a subset of the word "regulation[s]" in § 136v(a). A State is permitted to "regulate" (§ 136v(a)) the sale or use of pesticides, but only to the extent "[s]uch State" (§ 136v(b)) does not impose "requirements" (*id.*) that are in addition to or different from those in FIFRA. The "requirements" of § 136v(b), therefore, are viewed through the lens of the "regulation[s]" a State is permitted to issue in § 136v(a). *See Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995) ("a word is known by the company it keeps").

As this Court has unanimously concluded, the term "regulations" denotes "positive enactments." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 63 (2002). *See also Cipollone*, 505 U.S. at 519 ("the term 'regulation' most naturally refers to positive enactments by [legislatures and agencies], not to common-law damages actions"). As used in FIFRA, the term "regulation" is used the same way, for it would make no sense to say that a damages award acts as a "requirement" to "permit any sale or use prohibited by [FIFRA]." § 136v(a). To be sure, a state statute authorizing the sale or use of any state-registered pesticide would constitute a preempted "regulation" or "requirement" as to pesticides prohibited by EPA under FIFRA, but no court judgment could grant the same sale or use permission, which is purely a function of positive law. Whatever limits § 136v may impose on positive state labeling commands,

therefore, that section contains no textual indication of an intent to preempt state damages actions.[7]

In addition, Congress used the term "requirements" in § 136v(b) to refer to both state and FIFRA requirements. It prohibits state labeling "requirements" in addition to or different from "those required" (*i.e.*, "those [*requirements*] required") under FIFRA. It would be unnatural to read the word "requirements" more broadly in reference to a source of state law than for the federal government. *See Mohasco Corp. v. Silver*, 447 U.S. 807, 826 (1980) ("[W]e cannot . . . giv[e] the word 'filed' two different meanings in the same section of the statute.").

2. The preemptive "requirements" in § 136v(b) are narrow exceptions to broad regulatory authority conferred on States by § 136v(a)

The preemptive scope of § 136v(b) must be assessed in the context of § 136v(a), which is an "anti-preemption" provision that expressly authorizes States to regulate pesticides *more* stringently than EPA. Thus, a State (such as Texas) may completely ban the sale or use of a pesticide (such as Strongarm), even though EPA has registered the pesticide and approved its label. (A State, however, may not override federal law by permitting "any sale or use *prohibited by* [FIFRA]." § 136v(a) (emphasis added).)

As this Court stressed in *Mortier*, "§ 136v(a) . . . acts to ensure that the States could continue to regulate use and sales even where, such as with regard to the banning of mislabeled products, a narrow pre-emptive overlap might occur." 501 U.S. at 614. Plainly it makes no sense to con-

[7] This Court has squarely held that "field pre-emption cannot be inferred" from FIFRA. *Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597, 612 (1991). "To the contrary, the statute leaves ample room for States and localities to supplement federal efforts even absent the express regulatory authorization of § 136v(a). . . . The specific grant of authority in § 136v(a) . . . does not serve to hand back to the States powers that the statute had impliedly usurped." *Id.* at 613-14. It therefore is logical to read § 136v(a) and (b) as not intending to affect the common-law authority that States exercised prior to the 1972 Act.

strue § 136v(b) to foreclose the *lesser* regulatory effects that flow from damages actions that enable the pesticide manufacturer to choose to sell its products while assuming the risk of incurring common-law liability, when § 136v(a) gives States the far *greater* power to ban altogether sales and uses of the same product. Notably, the statutes at issue in *Cipollone* and *Medtronic* did not contain similar provisions conferring such sweeping regulatory authority on States, so this Court did not address whether Congress intended "requirements," in a statutory context analogous to FIFRA, to encompass the less stringent rulemaking directives of common-law liability.

3. Section 136v(b) addresses label commands, not actions that indirectly induce label changes

The limited scope of § 136v(b) also must be understood in light of the interplay between that provision and § 136v(a) and (c), which authorize States to apply indirect pressure on pesticide manufacturers that might induce a change to their labels. Holding state-law claims preempted is contrary to that intent.

Section 136v(a) permits a State to restrict or completely prohibit pesticide sales and use for any reason – including the State's perception that the label's warning is inadequate or the product is misbranded. Like a substantial damages award, those restrictions may induce pesticide manufacturers to seek EPA approval for a label alteration. Alternatively, a manufacturer may be induced to request EPA approval to change its label to promote additional pesticide uses approved by States under § 136v(c) that EPA has not approved. Section 136v(c) acts as an exception to § 136v(b) by conferring additional authority on States with respect to pesticide registrations to meet "special local needs." § 136v(c)(1). Indeed, EPA has interpreted § 136v(c) to permit States *directly* to "require supplemental labeling" when they determine a pesticide should be classified for restricted use under state law but EPA has not done so under FIFRA. 40 C.F.R. § 162.153(e)(5); *see* 46 Fed. Reg. 2008, 2011-12 (1981).

Especially in view of such authority for direct labeling regulations, any indirect pressure to change a pesticide label does not frustrate Congress's purpose of establishing nationally uniform labels. If a State bans the use of a pesticide, then any change the manufacturer makes to the label (as approved by EPA) would not be preempted; there is no reason to treat labeling changes prompted by state-law damages liability any differently. Indeed, Dow's own actions here suggest that "uniformity" concerns can readily be accommodated. After causing devastating injury to the farmers' crops, Dow rushed through a "supplemental" label addition within *seven months* after the farmers first reported injury. That supplemental label – which states that it is for distribution *only* in Texas, New Mexico, and Oklahoma – advised growers in those states with lands having a soil pH of 7.2 or greater not to use the very product that Dow had warranted the year before as usable "in all areas where peanuts are grown," JA 175, and to use it in a substantially different manner in lesser pH soils.

Congress commonly distinguishes between state positive and common law for preemption purposes. For example, the Court recently found no preemption of common-law claims under the Federal Boat Safety Act, noting that construing the Act that way "does not produce anomalous results. It would have been perfectly rational for Congress not to pre-empt common-law claims, which – unlike most administrative and legislative regulations – necessarily perform an important remedial role in compensating accident victims." *Sprietsma*, 537 U.S. at 64. The Court unanimously reached that conclusion in construing a preemption provision with a more definitive preemptive scope than FIFRA: "a State may not establish, continue in effect, or enforce a law or regulation establishing . . . or imposing a requirement." *Id.* at 58-59.[8]

[8] *See also Cipollone*, 505 U.S. at 518 ("[T]here is no general, inherent conflict between federal pre-emption of state warning requirements and the continued vitality of state common-law damages actions."); *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185-86 (1988) ("The

4. Section 136v(b) must be construed applying the presumption against preemption

Any doubt about Congress's intent in using the word "requirements" – or in construing the scope of § 136v(b), *see infra* Parts II and III – must be resolved *against* preemption. The Court has "long presumed that Congress does not cavalierly pre-empt state-law causes of action," especially where "Congress has 'legislated . . . in a field which the States have traditionally occupied.'" *Medtronic*, 518 U.S. at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).[9] Agriculture and consumer protection are plainly such "traditional" state-law fields.

As this Court said in the FIFRA context in *Mortier*, preemption analysis "'start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" 501 U.S. at 605 (quoting *Rice*, 331 U.S. at 230). The *Mortier* Court then applied that long-standing presumption against federal preemption of state law by holding that FIFRA does not preempt pesticide regulation by local governments, even though § 136v expressly authorizes "States" to regulate pesticides but is silent with respect to whether local governments may also do so. The Court found § 136v's "[m]ere silence" on the question "wholly inadequate to convey an express preemptive intent." *Id.* at 607. Here, too, the statute is

effects of direct regulation . . . are significantly more intrusive than the incidental regulatory effects of such an additional award provision. . . . Congress may reasonably determine that incidental regulatory pressure is acceptable, whereas direct regulatory authority is not."); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984) ("Congress intended to stand by both concepts [of federal regulation and state damage liability] and to tolerate whatever tension there was between them. We can do no less.").

[9] *See also, e.g., New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654-55 (1995) (applying presumption and finding no preemption) (citing *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985)); *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 740 (1985).

silent on preemption of damages claims, and congressional purposes underlying FIFRA are not served by broadly construing "requirements" to foreclose the types of state-law claims that were routinely brought against manufacturers to redress injuries caused by pesticides.

B. FIFRA's Structure Confirms That Congress Did Not Intend To Preempt State-Law Claims

The extensive use of "requirements" throughout FIFRA shows that Congress had no intent to preempt damages actions that might indirectly spur a pesticide manufacturer to alter the label of a faulty product. The term "requirements" is used 75 times in the remainder of FIFRA, including in the context of both labeling and state-law requirements, and each time refers only to direct commands arising out of statutory or regulatory enactments.

The use of "requirements" throughout FIFRA demonstrates that Congress understood labeling "requirements" to refer only to labeling commands imposed by statute and regulation, and it used the term "requirements" to denote a subset of "regulation[s]," a term connoting positive commands of law. "Requirements" should be construed the same way in § 136v(b). *See, e.g., Ratzlaf v. United States*, 510 U.S. 135, 143 (1994) ("A term appearing in several places in a statutory text is generally read the same way each time it appears."); *Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 479 (1992) ("identical terms within an Act bear the same meaning").

For example, EPA may register a pesticide only if "its labeling . . . compl[ies] with the requirements of [FIFRA]." § 136a(c)(5)(B). A pesticide is "misbranded" if its "labeling" fails to conform to the classification "requirements" imposed by § 136a(d). § 136(q)(1)(F), (G). Another provision, entitled "Requirements," bars pesticide labels that "conflict with or detract from any statement required by law or the Administrator as a condition of registration." § 136a(c)(9)(B). And § 136q(a)(1)(B) provides that EPA regulations "may require" that "the labeling of a pesticide contain requirements and procedures for the transportation, storage, and disposal of the pesticide." Because FIFRA refers exclusively to labeling "requirements" imposed under that Act, § 136v(b) should not be read more broadly to encompass state-law damages actions.

FIFRA's numerous other uses of the term "requirements" likewise encompass only positive law. Various provisions refer specifically to FIFRA's own "data requirements,"[10] "recordkeeping requirements" (§§ 136f(a), 136i-1(a)), "time requirements" (§§ 136d(b), 136w(a)(2)(C), 136w(d)(1)), and "registration requirements" (§§ 136a(h), 136m(a)(2)(A)). Additional references point to the "requirements" found in specific sections of FIFRA.[11] Other

[10] *See* § 136a(c)(2)(A) ("data requirements . . . with respect to minor uses"); § 136a(c)(2)(B)(viii)(I)(A) ("data requirements" for registration); § 136a(c)(2)(B)(viii)(III) ("process to . . . alleviat[e] future disparities between Federal and State data requirements"); § 136a(c)(2)(E) (EPA "may waive otherwise applicable data requirements"). Other provisions address "data requirements." § 136a(h)(4)(B); § 136a-1(a)(1), (b)(4), (c)(1)(C), (f)(1), (f)(1)(B); § 136d(f)(3)(D), (f)(4); § 136q(a)(1).

[11] *See* § 136(q)(1)(F) (pesticide is "misbranded" if label omits § 136a(d) "requirements"); § 136(q)(1)(G) (same); § 136a(b)(2) ("requirements" of an experimental use permit); § 136a(c)(2)(B)(iv) ("requirements that served as a basis for the notice of intent to suspend"); § 136a(c)(6) (denial of registration for failure to satisfy "requirements" of § 136a(c)(5)); § 136a(g)(1)(A) ("requirements" of section 136d); § 136a(h)(3)(C) ("requirements" of § 136a(c)(3)); § 136a-1(a)(2) ("requirements" of § 136a(c)(5)); § 136a-1(e)(1)(A) ("requirements" of § 136a and "the regulations issued under such section"); § 136a-1(e)(1)(B) (same); § 136a-1(e)(1)(D) (same); § 136a-1(e)(4)(A)(iv) (same); § 136a-1(g)(2)(C) ("requirements" of § 136a(c)(5)); § 136a-1(j) (exemption from "requirements" of § 136a-1(d)-(f), (i)); § 136g(c)(1) (civil and criminal proceedings for failing to comply with requirements of this subchapter); § 136i-1(e) (requirements of this section do not affect state or federal laws); § 136j(b)(1) (exemption from penalties for compliance with requirements of this subchapter); § 136k(b)(3) (seizure of pesticides that cause harm but comply with requirements of this subchapter); § 136q(f)(1)(C) (exemptions from requirements of this subsection); § 136w(b) (exemption from requirements of this subchapter); § 136w-1(b) ("requirements" of § 136i).

references to "requirements" point to EPA regulations[12] and other federal statutes.[13]

Significantly, FIFRA's references to "requirements" *of state law* encompass only positive law commands. *See* § 136i(a)(1) ("[T]he Administrator, in consultation with the Governor of such State, shall conduct a program for the certification of applicators of pesticides. Such program shall conform to the requirements imposed upon the States under the provisions of subsection (a)(2) of this section . . . ."); § 136w-2(a) (referral of complaint to "State officials for their investigation of the matter consistent with the requirements of [FIFRA]"); *see also* § 136w-5 ("Each State may establish minimum requirements for training of maintenance applicators and service technicians."). And other provisions of FIFRA contain usage similar to § 136v(b)'s use of "requirements" as a subset of the positive-law "regulations" in § 136v(a). Thus, EPA "may by *regulation* . . . issue *requirements*" regarding pesticide storage and transportation. § 136q(a)(2)(A), (3)(A) (emphases added). It also "may by *regulation* . . . issue *requirements*" for disposing of certain pesticides and containers. § 136q(a)(2)(B)-(C), (3)(B)-(C) (emphases added). In sum, not a single one of the 75 uses of "requirements" from the 1972 Act or the 1978 amendments can be read to refer to common-law damages actions. Every use of "requirements" clearly encompasses commands imposed only by statute or regulation.

The *Medtronic* plurality similarly relied on the fact that neighboring subsections of the statutory provision at issue there – and unlike the statute at issue in *Cipollone* – used the term "requirements" to "refer only to statutory and

[12] *See* § 136a(h)(3)(A)(ii) ("[r]equirements" for proposed regulations addressing antimicrobial pesticides); § 136a(h)(3)(B)(iii) ("[r]equirements" for final regulations); § 136q(a)(2)(A)-(C) (EPA authority to "issue . . . requirements and procedures"); § 136q(a)(3)(A)-(C) (same).

[13] *See* § 136a-1(g)(2)(E)(ii) ("requirements" of Federal Food, Drug, and Cosmetic Act); § 136q(f)(1)(B)(iv) ("requirements" of Solid Waste Disposal Act); § 136q(f)(3) (same); § 136q(h)(1) (same).

regulatory law that exists pursuant to the [statute] itself, suggesting that the pre-empted 'requirements' established or continued by States also refer primarily to positive enactments of state law." 518 U.S. at 489. The textual evidence here, however, is far stronger than in *Medtronic*. There, the use of "requirements" in the preemption clause itself did not refer back specifically to regulations Congress authorized States to promulgate in the same manner as § 136v(b),[14] whereas here the scores of other uses of "requirements" in FIFRA support a uniform and consistent interpretation of "requirements" in § 136v as limited to those rules deriving from positive law enactments. *See also Sprietsma*, 537 U.S. at 63 (finding that "Congress preempted only positive enactments" based on context in which "law or regulation" appeared in provision).[15]

C. FIFRA's Legislative History And Purposes Reveal No Intent To Preempt Damages Actions

When FIFRA was amended in 1972 to add § 136v(b), state-law damages actions against manufacturers had been common since the advent of the chemical pesticide industry. *See supra* pp. 4-5. And it was well-settled that

[14] The preemption clause at issue in *Medtronic* addressed "State and local requirements" in the provision's title. The substantive provision stated that "'no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement . . . which is different from, or in addition to, any requirement applicable under this chapter to the device.'" 518 U.S. at 481 (quoting 21 U.S.C. § 360k(a)(1)). Unlike in § 136v(b), which cross-references a state "requirement" stemming from a "regulation" otherwise permitted in § 136v(a), the preemption clause in *Medtronic* contained no similar cross-reference.

[15] The Montana Supreme Court was persuaded by FIFRA's voluminous and consistent usage that § 136v preempts no common-law claims, and it observed that, despite the fact that many federal courts of appeals had held such claims preempted, none had "ever addressed the meaning of 'requirements' in the entire context of FIFRA . . . . It is inconceivable that Congress intended that § 136v(b) would be the only section of FIFRA in which the term 'requirements' includes the application of general rules of common law by judges and juries." *Sleath v. West Mont Home Health Servs., Inc.*, 16 P.3d 1042, 1051 (Mont. 2000).

FIFRA's labeling requirements set only minimum standards and thus did not preempt state-law damages actions for failure to warn.[16] Aware of that background, Congress thus perceived no need to include a private right of action for damages in FIFRA.

In *Mortier*, this Court held that the legislative history of § 136v(b) concerning whether local governments were preempted from regulating pesticides was "complex and ambiguous," 501 U.S. at 612, and that a "disagreement" on that issue between "the two principal committees responsible for the bill . . . falls far short of establishing that preemption of local pesticide regulation was the 'clear and manifest purpose of Congress,'" *id.* at 610. The history on the issue presented here is far clearer. According to a comprehensive review of the voluminous legislative history of the 1972 FIFRA amendments by the U.S. Department of Justice, no witness or Member of Congress ever suggested that the proposed legislation would shield pesticide manufacturers from product liability tort suits. *See* Amicus Br. for United States at 5-6, 18-19, *Etcheverry v. Tri-Ag Serv., Inc.*, No. S072524 (Cal. filed Mar. 23, 1999), *available at* https://www.citizen.org/documents/usetcheverrybrief.pdf. Indeed, there is not even a single mention of such a notion. *Id.* That omission is striking, given the testimony estimating the personal toll attributable to pesticides per year at 200 to 800 deaths and 60,000 to 80,000 injuries.[17] As the U.S. has concluded, "[g]iven

[16] *See, e.g., Hubbard-Hall*, 340 F.2d at 405 (no FIFRA preemption); *Griffin v. Planters Chem. Corp.*, 302 F. Supp. 937, 944 (D.S.C. 1969) ("Aside from the requirements set forth for the label by the Secretary of Agriculture, [defendant] had a duty to use a label, or furnish a warning commensurate with the danger."); *Rumsey v. Freeway Manor Minimax*, 423 S.W.2d 387, 394 (Tex. Ct. App. 1968) (FIFRA does not "purport[] to change the common law duty to warn . . . [but] merely set[s] minimum standards").

[17] *See Federal Pesticide Control Act of 1971: Hearings before the House Comm. on Agriculture*, 92 Cong., 1st Sess. 708 (1971); *Federal Environmental Pesticide Control Act: Hearings before the Subcomm. on Agricultural Research and General Legis. of the Senate Comm. on Agriculture and Forestry*, 92 Cong., 1st Sess. 161, 168-71, 172-86 (1971); H.R. Rep. No. 92-511, at 71 (1971); S. Rep. No. 92-970, at 27 (1972).

that FIFRA establishes no private damages remedy for those injured by pesticides, it would be astonishing that, without any discussion, Congress could have intended to deprive injured persons of all means of relief." *Id.* at 6; *Silkwood*, 464 U.S. at 256. *See also* Amici Br. for Western Peanut Growers Ass'n *et al.*

The *Medtronic* plurality rejected a similar argument under the Medical Device Amendments, finding the argument for preemption "not only unpersuasive, [but] implausible." 518 U.S. at 487. Absent a federal private cause of action, preemption of state-law damages actions would effectively bar compensatory relief to injured persons and "would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation." *Id.* In view of the industry's position that any such liability would induce a change in the pesticide's label, affirming the Fifth Circuit's decision would produce a similarly perverse effect under FIFRA.

D. Neither The Fifth Circuit's Nor The Government's New Preemption Analysis Is Persuasive

Like other courts that have upheld a broad preemption under FIFRA, the Fifth Circuit assumed that § 136v(b)'s use of the word "requirements" necessarily ends the analysis. *See* Pet. App. 11a (citing *Andrus v. AgrEvo USA Co.*, 178 F.3d 395, 398 (5th Cir. 1999)). The court made no effort to consider the contextual placement of "requirements" in the preemption provision, as this Court did in *Medtronic*, or the overwhelming textual and contextual evidence that Congress could not possibly have meant to foreclose state lawsuits when it used the word "requirements" in § 136v(b).

In that respect, the court below followed mechanistically other court of appeals' decisions finding that FIFRA preempts state failure-to-warn damage claims, many of which

were decided before *Medtronic*. Those cases in turn had applied *Cipollone* based largely on the fact that "requirements" appeared in both statutes. They made no serious examination of the very different statutory text and structure of FIFRA.[18] Even after this Court decided *Medtronic* – which made plain that "requirements" must be interpreted in its statutory context – some courts have considered themselves bound by pre-*Medtronic* precedent (and declined to rehear the issue *en banc*). *See, e.g., Netland v. Hess & Clark, Inc.*, 284 F.3d 895, 899 (8th Cir. 2002).

In *Etcheverry*, the United States recognized that the prevailing approach among federal courts contained no analytic force. In a powerful brief, the government argued that § 136v(b)'s use of "requirements" did not foreclose state-law actions to redress pesticide injuries. The government now has adopted a position 180 degrees opposite to its careful, detailed, and analytical brief in *Etcheverry*, which it reiterated in *Hart v. Bayer Corp.*, 199 F.3d 239 (5th Cir. 2000). Because the government's *amicus* briefs filed in *Etcheverry* and *Hart* were filed with the Solicitor General's authorization, *see* 28 C.F.R. § 0.20(c), the government's reversal of position now is entitled to no weight or deference. *See, e.g., Norfolk S. Ry. v. Shanklin*, 529 U.S. 344, 356 (2000) ("no such deference is appropriate" where government's position "contradicts the agency's own previous construction"); *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (degree of deference depends, *inter alia*, on consistency and formality of government's position).

[18] *See, e.g., King v. E.I. DuPont De Nemours & Co.*, 996 F.2d 1346, 1350-51 (1st Cir. 1993); *Worm v. American Cyanamid Co.*, 5 F.3d 744, 747 (4th Cir. 1993); *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1023-25 (5th Cir. 1994); *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 370-71 (7th Cir. 1993); *Bice v. Leslie's Poolmart, Inc.*, 39 F.3d 887, 888 (8th Cir. 1994); *Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555, 559-61 (9th Cir. 1995); *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 981 F.2d 1177, 1178-79 (10th Cir. 1993); *Papas v. Upjohn Co.*, 985 F.2d 516, 518 (11th Cir. 1993) (per curiam).

II. PETITIONERS' CLAIMS ARE OUTSIDE THE SCOPE OF § 136v(b) PREEMPTION

Even if this Court were to conclude that the word "requirements" in § 136v(b) can include state-law damages actions, it does not follow that *all* such claims are barred. The 1972 Act did not "transform[] FIFRA into a comprehensive statute that occupied the field of pesticide regulation." *Mortier*, 501 U.S. at 612. Yet Dow's theory of preemption, as accepted by the court below, would functionally do that: any claim with even an "indirect[]" effect (Pet. App. 11a) on a label is preempted. The court failed to conduct a nuanced analysis of the farmers' claims to determine whether they are consistent with § 136v(b).

For three distinct reasons, those claims survive. *First*, Congress specifically amended FIFRA to eliminate a requirement that EPA evaluate a pesticide's efficacy, so § 136v(b)'s "requirements" do not properly encompass common-law claims addressing efficacy. *See Medtronic*, 518 U.S. at 484-85 (interpreting scope of express preemption provision in light of congressional purposes and presumption against preemption); *id.* at 507-08 (Breyer, J., concurring in part and in the judgment) (scope of word "requirement" should be informed by "read[ing] the pre-emption statute . . . in light of . . . basic pre-emption principles" of "'conflict' and 'field' pre-emption"); *Cipollone*, 505 U.S. at 518 (using conflict-preemption analysis to interpret scope of express preemption clause in 1965 Federal Cigarette Labeling and Advertising Act). *Second*, Congress flatly prohibited labels that are false and give inadequate instructions for use. The farmers' claims are parallel to, and not inconsistent with, those "misbranding" requirements. *See Medtronic*, 518 U.S. at 495; *see also id.* at 513 (O'Connor, J., concurring in relevant part) (state cause of action that seeks to enforce federal requirement not preempted). *Third*, the text of § 136v(b) itself only forecloses state requirements that are "in addition to or different from" "labeling or packaging" requirements imposed under FIFRA. Analysis of the elements of the farmers'

claims – which the court below did not conduct – establishes that strict liability, breach of express warranty, negligence, and fraud claims rest on legal duties that impose no alteration to an EPA-approved label.

A. EPA Has Waived Evaluation Of Whether A Pesticide Might Be Toxic To The Target Crop When Approving A Pesticide Label

Congress has expressly permitted EPA to waive any evaluation of the efficacy of pesticides prior to registration. Because FIFRA no longer imposes a duty on EPA to evaluate the efficacy of any federally registered pesticide, liability for the farmers' claims imposes no labeling requirements "in addition to or different from" those in FIFRA. The "requirements" preempted in § 136v(b), therefore, cannot include claims concerning the efficacy of pesticides. Yet the farmers' claims here for strict liability, fraud, negligence, and breach of warranty *are*, in effect, claims that Strongarm was ineffective.

1. For the past 26 years, Congress has expressly authorized EPA to register agricultural pesticides *without* evaluating whether they might cause crop damage. EPA regulations provide that a pesticide manufacturer need not submit "efficacy" data concerning: (1) "target area phytotoxicity," which is defined as whether the pesticide leaves the target crop unharmed, 40 C.F.R. § 158.540, or (2) "product performance," defined as whether the pesticide controls the target pest, *id.* § 158.640(b); *see also* U.S. Inv. Br. 4.[19] As applied to this case, those regulations mean that EPA registered Strongarm without evaluating whether it might (1) damage the farmers' peanut crop or (2) control the weeds it was designed to eradicate.

[19] Although EPA's regulations provide that "target area phytotoxicity" data are "required for Special Review and certain public health situations," 40 C.F.R. § 158.540(b)(1), and "product performance" data are required in certain cases concerning human health or where EPA on a case-by-case basis requires it, *id.* § 158.640(b)(1), those circumstances are inapplicable here.

FIFRA's 1972 amendments allowed EPA to register a pesticide only upon evaluating its proposed label and determining that its "composition is such as to warrant the proposed claims for it." § 136a(c)(5)(A). But EPA soon discovered that efficacy review diverted scarce resources from the agency's paramount responsibilities of protecting public health and the natural environment, so it requested from Congress the authority "to waive the efficacy data requirement when appropriate" – "particularly [with regard to] agricultural pesticides." H.R. Rep. No. 95-343, at 9 (statement of EPA Administrator Costle); *see also* H.R. Rep. No. 95-663, at 18 (1977) ("The registration and reregistration process, which is the foundation of the program, has come to a virtual halt.").

In 1978, Congress amended FIFRA by conferring on EPA the authority it had requested to waive efficacy requirements. *See* § 136a(c)(5) (final two sentences). Congress made clear that "[t]his authority is expected to be used, in particular with respect to *agricultural chemicals*." H.R. Rep. No. 95-663, at 19 (emphasis added); *see also id.* at 27 (authorizing waiver "whenever the Administrator found that some other procedure for assuring the efficacy of pesticide products appeared to be sufficient").

EPA waived its review of proposed label claims relating to pesticide efficacy, explaining that the waiver would enable it to focus on EPA's "primary mandate under FIFRA . . . [,] the health and safety aspects of pesticides." 47 Fed. Reg. 53,192, 53,196 (1982); *see* 40 C.F.R. § 158.640(b)(1); 40 C.F.R. § 158.540(b)(1). The agency found that efficacy review was unnecessary because efficacy claims are "effectively regulated by the marketplace." 44 Fed. Reg. 27,932, 27,938 (1979). That is, "pesticide producers are aware that they are potentially subject to *damage suits* by the user community if their products prove ineffective in actual use." 47 Fed. Reg. 40,659, 40,661 (1982) (emphasis added). As a result, EPA reviews pesticide labels for the adequacy of claims relating to human health and the natural environment – but *not* for "target area phytotoxic-

ity," *i.e.*, the farmers' crop damage. 40 C.F.R. § 158.540. Accordingly, there is no EPA action, rule, or decision that would conflict with the farmers' suit.[20]

In 1996, after several courts had found crop damage claims preempted by FIFRA based on EPA's supposedly "rigorous label-approval process," *Taylor AG Indus.*, 54 F.3d at 560, EPA issued a public notice ("PR 96-4") explaining that "courts have erroneously concluded that because a pesticide label contained warnings regarding property damage that EPA had necessarily evaluated such warnings and found them to be truthful and adequate. . . . [T]his Notice is intended to clarify that EPA's approval of a pesticide label does not reflect any determination on the part of EPA that the pesticide will be efficacious or will not damage crops or cause other property damage." JA 235. EPA also noted that, in previously exercising its power to waive efficacy review, it had "pointed to private legal actions for damages as one factor that would ensure that pesticide manufacturers sold an efficacious product." JA 230 (citing 47 Fed. Reg. at 40,659, 40,661).[21]

[20] The Texas Supreme Court found these considerations persuasive in holding that FIFRA does not preempt crop damage claims. *See American Cyanamid Co. v. Geye*, 79 S.W.3d 21 (Tex. 2002), *cert. denied*, 123 S. Ct. 2637 (2003). Although the California Supreme Court reached a contrary conclusion, it did so based on a fundamental error that assumed EPA's efficacy data waiver did not include the "target area phytotoxicity" waiver in 40 C.F.R. § 158.540. *See id.* at 28-29 (discussing *Etcheverry v. Tri-Ag Serv., Inc.*, 993 P.2d 366 (Cal. 2000)). As the government recognizes, the "target area phytotoxocity" data waiver in 40 C.F.R. § 158.540 is part and parcel of EPA's efficacy data waiver pursuant to the 1978 FIFRA amendments. *See* U.S. Inv. Br. 4, 13.

[21] In attempting to rationalize its changing position on FIFRA preemption, the government observes that PR 96-4 was not intended to "express a view on the proper interpretation of the text of FIFRA's preemption provision." U.S. Inv. Br. 13-14 n.3. But the government cannot contest that the notice's statements regarding EPA's waiver of efficacy review are *factually* accurate. *See id.* ("[PR 96-4] makes clear that, under the general registration procedures addressed in that notice, EPA had waived review of the efficacy of agricultural pesticides in the registration process."); *id.* at 13 n.2 ("Generally, EPA does not independently evaluate a registrant's product efficacy claims pertaining to agricultural pesticides."); *accord* Letter from Jonathan Z. Cannon, General Counsel, EPA, to Douglas T. Nelson, Vice President-General Counsel, American Crop Protection Ass'n (Nov. 14, 1996) ("In the notice, EPA explains that it does not review the accuracy of label claims regarding efficacy and the potential for crop damage. . . . It appears to EPA that [certain court decisions] evidence a lack of a full understanding of EPA procedures and regulations.").

EPA's decision not to evaluate efficacy claims when registering a pesticide finds a strong parallel to *Medtronic*, where the Court unanimously found that FDA approval of a pacemaker, under a standard requiring the agency to determine only whether the device was "substantially equivalent" to another device already on the market, did not constitute a preemptive "requirement." 518 U.S. at 493-94; *see also id.* at 513 (O'Connor, J., concurring in relevant part). The preemption provision in that case applied to requirements concerning "safety or effectiveness." FDA even conducted its substantial equivalence review of the pacemaker with some regard for those concerns, but its abbreviated review did not "require" the pacemaker to take any particular form. *Id.* at 493 (majority op.). Instead, the device was approved without "running the gauntlet" of the full approval process for a novel medical device. *Id.* at 493-94.

2. EPA approved the Strongarm label without requiring Dow to take any particular form with respect to target area phytotoxicity claims. Because EPA waived that requirement, there was no FIFRA or EPA labeling "requirement" to preempt the farmers' suit.

The government suggests that Dow submitted efficacy data to EPA in seeking expedited review of its Strongarm application, but it then admits that such data were "*not* [submitted for EPA review] in the context of label approval." U.S. Inv. Br. 16 (emphasis added). Instead, it concedes Dow submitted data under an expedited review provision (called the "Reduced Risk Initiative") only "to allow [EPA] to determine whether 'risk reduction has a

reasonable opportunity to be accomplished by adoption of the new pesticide by growers.'" *Id.* at 16 n.5 (quoting EPA PR 97-3 (JA 252)); *see also id.* at 13 n.2 (describing EPA's consideration of efficacy data under RRI as "circumscribed"). The government does not contend that EPA actually concluded, based on any such data, that Strongarm was safe for crops (or that the agency had any duty to assess such data). It is illogical to infer that EPA would fully evaluate target area phytotoxicity data under an *expedited* review provision when it undisputedly does not do so in a full review. The agency's regulations make clear that, if "part 158" does not require submission of efficacy data (it does not), then EPA does *not* "determine[] that the composition of the product is such as to warrant the proposed efficacy claims for it." 40 C.F.R. § 152.112(d).

Dow, on the other hand, appears to claim that EPA evaluated Strongarm's efficacy and relies on an inapposite EPA reference to Dow's proposed peanut "'plantback restrictions'" (*i.e.*, the required interval of time before a new crop can be planted on the same land). Dow Cert. Opp. 2 (quoting 65 Fed. Reg. 12,129, 12,133 (2000)). But EPA's statement was not made in the context of a FIFRA registration or an evaluation of the potential for crop damage. Rather, it concerns the agency's evaluation of Dow's request to establish a safe tolerance for diclosulam in the *food* supply, pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 346 (entitled "Tolerances for poisonous or deleterious substances in *food*; regulations") (emphasis added). *See* 40 C.F.R. Pt. 180 (entitled "Tolerances and Exemptions from Tolerances for Pesticide Chemicals in *Food*") (emphasis added); *see also* JA 233 ("EPA's concern is that the consumption of the rotated crop would increase *dietary* exposure to the pesticide residue. Rotational crop restrictions are not reviewed to determine if the rotated crop would be injured by the residual pesticide residues.") (emphasis added). Those *human*

health standards have nothing to do with the issue here: whether diclosulam causes damage to crops.[22]

In fact, the evidence specifically confirmed that "Dow AgroSciences LLC had not submitted any target area phytotoxicity studies or data on peanuts treated with diclosulam" and that the "EPA did not require Dow AgroSciences LLC to submit data concerning target area phytotoxicity for peanuts." JA 216. As an EPA agent explained to petitioners' expert, "EPA did not evaluate whether diclosulam (Strongarm) had a toxic effect on peanut plants." *Id.*[23]

To be sure, EPA has generally reserved the right subsequently to request efficacy data, but the potential for a follow-up assessment in no way affects its initial, conditional registration of Strongarm without having decided whether target-area phytotoxicity might render Dow's effi-

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[22] Although both FIFRA and EPA regulations require the agency to "publish in the Federal Register . . . a notice of each application for registration of any pesticide if it contains any new active ingredient" and to provide for public "comment," § 136a(c)(4); *see* 40 C.F.R. §§ 152.102, 152.119, it apparently did not do so for Strongarm. The only public notice petitioners have been able to locate in the Federal Register lists Dow's petition to establish a food tolerance for diclosulam, but not its registration of Strongarm. *See* 63 Fed. Reg. 64,484, 64,488-89 (1998).

[23] In a carefully worded affidavit submitted by Dow employee Dr. John J. Jachetta, Dow did not dispute that omission. *See* JA 219-23. That affidavit does not claim that Dow submitted target-area phytotoxicity studies, but it does claim that Dow submitted "studies evaluating the effects of Strongarm on Seedling emergence and vegetative vigor of *non*-target terrestrial plants." JA 223 (emphasis added). Importantly, whatever plants were involved in those studies, Jachetta surely would have highlighted studies submitted by Dow to EPA that concerned potential damage to peanuts. The omission in his affidavit is glaring. In addition, Jachetta's RRI submission to EPA contains only a brief summary of efficacy studies. Those studies appear to be focused entirely on whether the product will control weeds – not target-area phytotoxicity. *See* J. Jachetta, *et al.*, *Reduced Risk Rationale for Diclosulam Herbicide Used in the Control of Broadleaf Weeds in Peanuts* 24 (1998). (Although no discovery has occurred in this case, petitioners obtained this document from EPA through the Freedom of Information Act. Petitioners will promptly lodge this material with the Court upon request.)

cacy claims "false or misleading" and its Strongarm product "misbranded." § 136(q)(1)(A); *see also* § 136a(c)(5). The Court in *Medtronic* similarly found no preemption even though the pacemaker approved under the FDA's substantial-equivalence procedure had a continuing duty to satisfy the FDA's standards pertaining to "labeling[] and the misbranding and adulteration provisions of the Act." *Medtronic*, 518 U.S. at 493 (quoting FDA letter).[24] As in *Medtronic*, so too here the farmers' claims are not preempted. Agency inaction – based on Congress's repeal of the statutory requirement that EPA verify efficacy claims before registering a pesticide – cannot preempt in this circumstance. *Sprietsma*, 537 U.S. at 64-65 (rejecting reliance on Coast Guard's decision "not to adopt a regulation requiring propeller guards on motorboats"); *Freightliner*, 514 U.S. at 286-87 (rejecting preemption where federal agency "did not decide that the minimum, objective safety standard required by [federal statute] should be the absence of all standards, both federal and state").

Interpreting § 136v(b) to preempt state-law damages actions challenging label claims regarding pesticide efficacy creates a dilemma for EPA unintended by Congress: to divert resources away from its primary mission of protecting human health and the natural environment to regulate pesticide efficacy or to let pesticide efficacy go unchecked knowing that States are preempted from filling this void. There is no evidence that, in enacting § 136a(c)(5) and § 136v(b), Congress intended to leave pesticide efficacy unmonitored by preempting state-law claims. Because Congress wanted EPA to devote its limited resources to public health and natural environment issues, FIFRA should not be interpreted as preempting state-law damages actions regarding pesticide efficacy.

[24] *Compare* 21 U.S.C. § 352(a) ("A drug or device shall be deemed to be misbranded . . . [i]f its labeling is false or misleading in any particular.") *with* 7 U.S.C. § 136(q)(1)(A) ("[a] pesticide is misbranded if . . . its labeling bears any statement . . . which is false or misleading in any particular").

The Court "should not impute to Congress a purpose to paralyze with one hand what it sought to promote with the other." *American Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 513 (1981) (internal quotation marks omitted).[25]

B. Petitioners' Claims Are Consistent With FIFRA's Misbranding Requirements

Even aside from EPA's waiver of review of efficacy claims, the farmers' claims are not preempted because they are completely consistent with FIFRA's prohibition on any distributed or sold pesticide that is "misbranded." § 136j(a)(1)(E). A pesticide is "misbranded" if its label is "false or misleading," contains inadequate "directions for use," or omits a necessary "warning or caution statement." § 136(q)(1)(A), (F), (G). State-law damages claims – even for failure to warn – would not impose a labeling or packaging requirement "in addition to or different from" those FIFRA misbranding prohibitions. § 136v(b). Instead, such claims would be consistent with the misbranding prohibitions by giving a remedy to injured farmers for the pesticide manufacturer's failure to ensure that its label is accurate, a requirement imposed by federal law.[26] To the ex-

[25] These are not simply theoretical concerns. DDT was banned ultimately because of its hazardous environmental consequences, but not until many years after the first lawsuits were filed asserting injuries from DDT. *See supra* p. 2. Other pesticides have been the cause of deaths to persons from acute pesticide poisoning. *See* H. Wellford, *Sowing the Wind* 219-28 (1972). It is thus perfectly logical for Congress to entrust to EPA the tasks of evaluating pesticides for those harms, while leaving to private remedial enforcement through common-law suits the types of crop damage caused by pesticides. Indeed, numerous provisions of FIFRA entrust EPA with responsibility to safeguard the environment and public health, a statutory directive in sharp contrast to Congress's mandate with respect to pesticide efficacy. *See, e.g.*, § 136a(c)(5)(C), (D) (EPA to approve pesticides that do not produce "unreasonable adverse effects on the environment").

[26] This Court need not determine that the farmers are asserting that Dow violated FIFRA in its various particulars to uphold their claims under this theory. Rather, it is sufficient that the farmers allege that Dow's label falsely warranted its product. Those claims are consistent with FIFRA's general prohibition on misbranding. *See Med-*

tent Dow's actions are inconsistent with the standards imposed by federal law, a state-law suit to remedy such injuries would not be preempted, as this Court held unanimously in *Medtronic* under a preemption provision that likewise applied to state requirements "different from, or in addition to," federal law. *See* 518 U.S. at 495; *id.* at 513 (O'Connor, J., concurring in relevant part).[27]

The absence of any state requirement at variance with a federal standard is made even clearer by the fact that EPA has not imposed a government-worded statement on the Strongarm label with which a state-law damages judgment might conflict. *Cf. id.* at 504 (Breyer, J., concurring in part and in the judgment) (concluding that a state-law requirement of a one-inch hearing-aid wire would be preempted if federal law required a two-inch wire). Rather, EPA permitted *Dow*'s proposed language, which claimed that "Use of Strongarm is recommended in all areas where peanuts are grown." JA 86, 108, 175. Neither FIFRA nor EPA "required" Dow to make or to prove that particular claim of efficacy. If Dow's claims of product efficacy were false, misleading, or otherwise misbranded as defined in FIFRA, then a state-law damages action relying on a parallel misbranding standard would be consistent with, and thus not "in addition to or different from," federal requirements. The mere fact that state-law claims require proof of additional elements (such as breach of a common

tronic, 518 U.S. at 495 (rejecting preemption in situation where "precise contours of [plaintiffs'] theory of recovery have not yet been defined" because "pre-emption issue was decided on the basis of the pleadings"). Petitioners will have ample time, and Dow sufficient notice, to litigate those claims as discovery proceeds.

[27] Indeed, the government recently endorsed this reasoning in a brief to this Court (which withdrew the positions it had advanced in the *Etcheverry* case), explaining that the Court's "unanimous[]" holding in *Medtronic* means that FIFRA "does not bar common law tort claims that are based on a violation of federal regulations – *i.e.*, where federal regulations furnish the standard of care." Amicus Br. for United States at 13, *American Cyanamid Co. v. Geye*, No. 02-367 (U.S. filed May 30, 2003) ("U.S. *Geye* Amicus Br.").

law duty) would not, in itself, impose a requirement different from FIFRA; the burden, after all, would be on the injured party and not the manufacturer to establish such proof. *See Medtronic*, 518 U.S. at 494; *id.* at 513 (O'Connor, J., concurring in relevant part) ("To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ.").

FIFRA also provides that "[i]n no event shall registration of an article be construed as a defense for the commission of any offense under [FIFRA]." § 136a(f)(2). If the mere fact that a pesticide has been registered is no defense to a misbranding charge by EPA, then there is no reason to find it a defense preempting a damages action.[28]

Enforcing a misbranding prohibition through state-law claims is also consistent with FIFRA's continuing duty on registrants to report adverse effects that may indicate the need for a change in the label. *See* 40 C.F.R. § 159.184 ("Toxic or Adverse Effect Incident Reports"); § 136d(b) (EPA may cancel registration "[i]f it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of [FIFRA]"). Accordingly, state-law damages actions support – not undermine – the federal mislabeling requirements. *See* U.S. Inv. Br. 4 ("EPA requires the registrant, after a pesticide has been registered, to report incidents of known harm to non-target organisms, such as crops, if the pesticide label does not provide adequate notice of the risk of such harm."). State-law claims provide a means for manufacturers to assess which incidents of pesticide harm merit reporting to EPA.

[28] In a state damages suit, the plaintiff bears the burden of persuasion, whereas in an EPA cancellation or suspension action the pesticide manufacturer "has a continuing burden of proof to establish that its product is entitled to registration." *Dow Chem. Co. v. Ruckelshaus*, 477 F.2d 1317, 1324 (8th Cir. 1973); *see* 40 C.F.R. § 164.80(b).

C. The Farmers' Claims Do Not Add "Different" Requirements Under § 136v(b)

Even if preemption were not avoided by EPA's waiver of efficacy review or the farmers' state-law claims imposing only parallel requirements to FIFRA, their suit still would not be barred. Proof of the elements of the farmers' claims does not impose requirements "in addition to or different from" FIFRA's labeling or packaging requirements.

1. The strict liability claims are not preempted

The farmers allege that Strongarm was at all relevant times within the exclusive control of Dow when it was "designed, formulated, developed, produced, manufactured and sold." JA 189. Dow therefore is liable for defective design in the rendering of an unreasonably dangerous product under state strict liability principles. The court below deemed that cause of action equivalent to a "failure to warn" claim subject to preemption. Pet. App. 19a. It reasoned that, to avoid future liability, a manufacturer would have to alter the label, an act the court presumed would be foreclosed under § 136v(b). *Id.*

The error in the court's analysis, however, is that breach of a duty – a "failure to warn" – is not dispositive in analyzing a strict liability claim. In fact, the elements of strict liability are a defective product that was unreasonably dangerous, the defect arose when the product was in the defendant's control, and injury to the plaintiff. *See Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 336-38 (Tex. 1998) (rejecting argument that fair warning can foreclose strict liability claim "as a matter of law"). Strict liability claims "mak[e] the seller subject to liability to the user or consumer *even though he has exercised all possible care in the preparation and sale of the product.*" *Restatement (Second) of Torts* § 402A cmt. a (1965) (emphasis added). Under Texas strict liability law, the warning contained on a label is at best a factor for the jury to consider, and not a dispositive consideration as a matter of law. *See Uniroyal*, 977 S.W.2d at 336 ("'[W]hen a safer design can reasonably be implemented and risks can reasonably be designed out of a product, adoption of the safer design is required over a warning that leaves a significant residuum of such risks. . . . Warnings are not . . . a substitute for the provision of a reasonably safe design.'") (quoting *Restatement (Third) of Torts: Product Liability* § 2, cmt. *l* (1998)) (emphasis omitted).

Moreover, in this case, Dow marketed Strongarm to west Texas farmers whose lands have a pH of 7.2 or higher. *See* JA 125, 179. Dow has now admitted in its supplemental label that Strongarm is *never* safe to use in such soils. *See* JA 181 ("Do not apply Strongarm to soils with a pH of 7.2 or greater."). This is not a case, therefore, where a label warning could ever make the product safe for use on farms with high pH soil. Because only a redesign of the product could do so, the farmers' claims are completely unaffected by any type of failure to warn theory. It is illogical for Dow to contend that it may market an unreasonably dangerous product and then claim preemption because a label warning could have said not to use the product at all. Indeed, the result of a damages action confirming what Dow has now admitted – that Strongarm can *never* be used in soils with a pH of 7.2 or greater and that *no* label warning could render it safe for use there – would at most have only the indirect effect of banning or restricting the use of the pesticide in those areas, which is precisely the type of direct authority § 136v(a) preserves for States.

Even in reversing its position on FIFRA preemption, the U.S. acknowledges that strict liability claims should survive. *See* U.S. *Geye* Amicus Br. at 13 ("[A] claim based on strict liability . . . need not be based on statements in labeling at all."). Because a strict liability claim does not contain as an element any breach of duty or failure to warn on the manufacturer's part, common-law liability for such a claim cannot impose a "requirement" with respect

to labeling.[29] Such claims were routinely upheld against pesticide manufacturers before and after the 1972 Act.[30] The same result should govern now.

2. The express warranty claims are not preempted

The farmers allege breach of warranty (including claims under the Texas DTPA, which "establishes a remedy for the breach of an independent warranty," Pet. App. 17a) based on express warranties provided by Dow (1) on the label and (2) off the label and before the sale. *See* JA 185-89. Those warranty theories are not preempted, however, because FIFRA imposes no "requirements" with respect to

[29] Contributory negligence thus ordinarily is not a defense to a strict liability claim, except when the injured party "discovers the defect and is aware of the danger" and nonetheless "proceeds unreasonably to make use of the product and is injured by it." *Restatement (Second)* § 402A cmt. n. The dramatic changes in the Strongarm label in 2001 all but concede that the product was not suited for use on petitioners' farms, *see supra* pp. 11-12, so the 2000 label could not have given the farmers the requisite notice that would establish contributory negligence. The farmers also allege strict liability under *Restatement (Second)* § 402B, which provides strict liability when the seller of chattels makes "a misrepresentation of a material fact concerning the character or quality of a chattel sold by him" that causes injury, even in the absence of a fraudulent or negligent statement. *See* JA 189.

[30] *See, e.g., Streich v. Hilton-Davis*, 692 P.2d 440 (Mont. 1984) (sufficient evidence to hold potato sprout suppressant manufacturer liable for negligence, breach of implied warranty, and strict liability for failure to warn of side effects harmful to potato crop); *Mortensen v. Chevron Chem. Co.*, 693 P.2d 1038 (Idaho 1984) (affirming JNOV for fungicide manufacturer against strict liability claim by buyer that chemical damaged seed potatoes because no proof that product was defective); *Shields v. Morton Chem. Co.*, 518 P.2d 857 (Idaho 1974) (reversing judgment for manufacturer of pesticide-fungicide for breach of warranty and strict liability because trial judge wrongly instructed jury that contributory negligence applied to both counts, when it applies only to negligence); *Rose v. Buffalo Air Serv.*, 104 N.W.2d 431 (Neb. 1960) (chemical company strictly liable for mispackaging chemicals to be sprayed on crops); *Chapman Chem. Co. v. Taylor*, 222 S.W.2d 820 (Ark. 1949) (manufacturer held strictly liable for breaching duty to test for crop damage caused by extrahazardous chemical).

express warranties. But, having made such warranties, Dow was obliged to make them true.

First, the label expressly provides that "Dow AgroSciences *warrants* that this product . . . is reasonably fit for the purposes stated on the label." JA 111 (emphasis added); *see also* JA 111-12. Indeed, Dow admitted, and the district court held, that "Strongarm's label provisions . . . provided a limited express warranty." CA App. 313; Pet. App. 26a n.1; *see also* JA 208. The "purposes" to which Dow's express warranty refers include the label representation that the "[u]se of Strongarm is recommended in *all* areas where peanuts are grown." JA 108, 175 (emphasis added). *Second*, the farmers relied on off-label representations made prior to their purchase of Strongarm by Dow's agents, who trumpeted that Strongarm was reasonably fit for use on peanuts and would yield "excellent" results in west Texas soil.[31] Under neither theory are the farmers' claims preempted.

a. The court based its conclusion that the on-label express warranty claim was preempted on the ground that the farmers' success in a damages suit "would provide a manufacturer with a strong incentive to alter its label to avoid future liability." Pet. App. 16a. That conclusion went beyond the far more limited text of § 136v(b), which preempts only state-law "requirements" that differ from or add to FIFRA "requirements" – but not claims that might induce a pesticide manufacturer to alter its product label.

As the *Cipollone* plurality instructed, the court should instead have assessed whether the "legal duty that is the predicate of the common-law damages action constitutes a [state-law] 'requirement'" under the preemption provision. 505 U.S. at 523-24. Because "[a] manufacturer's liability

[31] The evidence on this point is developed as to some of the farmers through affidavits. *See* JA 147-48, 152-53, 157-58. The absence of evidence as to other farmers at this early stage of the litigation (prior to full discovery) should not foreclose other petitioners on remand from advancing claims based on this theory of liability.

for breach of an express warranty derives from, and is measured by, the terms of that warranty . . . , the 'requirements' imposed by an express warranty claim are not 'imposed under State law,' but rather imposed *by the warrantor*" and thus are not preempted. *Id.* at 525 (alteration omitted); *see also id.* at 525 n.23 ("express warranty claims . . . sound in contract rather than in tort").

Under that analysis, the on-label, express warranty claims are not preempted "labeling requirements" because they are not imposed under state law. Instead, they derive solely from Dow, the warrantor. *See id.* at 526 ("That the terms of the warranty may have been set forth in advertisements rather than in separate documents is irrelevant to the pre-emption issue . . . because, although the breach of warranty claim is made 'with respect to advertising,' it does not rest on a duty imposed by state law.") (alteration omitted); *see American Airlines, Inc. v. Wolens*, 513 U.S. 219, 228 (1995) (breach of contract suit not preempted by Airline Deregulation Act because "terms and conditions airlines offer and passengers accept are privately ordered obligations") (citing *Cipollone*, 505 U.S. at 526 (plurality op.)). Because nothing in FIFRA required Dow expressly to "warrant[]" that Strongarm "is reasonably fit for the purposes stated on the label" (JA 111), it is legally irrelevant that Dow felt "induce[d]" (Pet. App. 17a) to change its label to remove that warranty.

b. The Fifth Circuit also erred in holding that Dow's pre-sale, off-label statements promising the farmers "excellent" results in west Texas soils are preempted because they did not "deviate[]" from Dow's label claim that Strong-arm was "recommended in all areas where peanuts are grown" (JA 108, 175). *See* Pet. App. 17a. If those oral representations by Dow's agents merely reflect the label contents, then they should be enforceable just like the on-label warranty voluntarily provided by Dow. In any case, whether or not the off-label statements differed from the label, claims that those representations are false would

not be preempted because § 136v(b) does not preempt *any* off-label representations.[32]

Even assuming § 136v(b) could be read to preempt off-label claims that are similar to on-label claims, the pre-sale, off-label representations here were substantially different. While the label "recommended" Strongarm for use in "all" areas, the pre-sale, field-day representations were far more specific: they promised that Strongarm was "excellent" for use in "west Texas" soils. JA 147, 152, 190-91. Plainly, the farmers were interested in knowing whether Strongarm would be effective on their own lands, and that is the assurance they received from Dow, whose agents claimed that Strongarm was not merely recommended but would be "excellent" for their west Texas peanut crops. To be sure, the geography covered by the original label is broad enough to cover west Texas, but any farmer would know that soil, climate, and other essential farming conditions will vary by geography. (Indeed, that is borne out here by Dow's subsequent action: within months of the farmers' disastrous experience, Dow sought EPA approval to alter the label to exclude or substantially limit use in the areas in which Dow had once claimed Strongarm would yield "excellent" results.[33])

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[32] Even the federal government appears to accept this argument for non-preemption. In *Geye*, the government noted that "[m]agazine advertisements, as well as many types of brochures, are not within FIFRA's express definition of 'labeling.'" U.S. *Geye* Amicus Br. at 11. The government then notes that any evidence based on such off-label statements would not be preempted and would be admissible to establish liability for non-preempted claims. *See id.* at 11-12. Thus, to the extent the farmers' claims stem from off-label statements – which they undisputedly do (JA 190) – FIFRA does not preempt them even under the government's revised position.

[33] In the court below, Dow asserted (using a thesaurus) that the words "excellent" and "recommend" were synonymous. Appellee's Br. 36-37. There is no merit to that position. An "excellent" product is one that "excel[s] or exceed[s] in kind or degree," or is "meritoriously near the standard or model." *Webster's Third New International Dictionary* 791 (2002). By contrast, to "recommend" is to "praise" or "to mention

3. The fraud claims are not preempted

The farmers' fraud claims are based on the same types of representations as their express warranty claims, and are backed by the allegation and evidence that Dow marketed Strongarm to the farmers and recommended it for "all" areas despite having knowledge that scientific studies had shown diclosulam to be toxic to peanuts grown in the high pH soils commonly found in Texas, New Mexico, and Oklahoma. *See supra* pp. 8-9. As with the express warranty claims, the court below erred in holding the pre-sale representation claims preempted. *See* Pet. App. 16a-17a.

The court's overbroad focus trained only on whether success would "provide a manufacturer with a strong incentive" to alter its label "to avoid future liability." *Id.* at 16a. The court failed to assess the source of the legal duty for fraud, which *Cipollone* makes clear has nothing to do with labeling, but rests "on a more general obligation – the duty not to deceive." 505 U.S. at 528-29 (plurality op.). The *Cipollone* plurality found that fraud claims based on statements made in advertising were not preempted, even though the 1969 Public Health Cigarette Smoking Act prohibited state-law "requirement[s]" "with respect to . . . advertising." *Id.* at 515. "Unlike state-law obligations concerning the warnings necessary to render a product 'reasonably safe,' state-law proscriptions on intentional fraud rely only on a single, uniform standard: falsity." *Id.* at 529.

That analysis compels the conclusion that the farmers' fraud claims here, whether based on on-label or off-label representations, are not preempted. Indeed, the farmers' claim that Dow knew diclosulam was inappropriate for use in high pH soils is indistinguishable from the claim that

or introduce as being worthy of acceptance, use, or trial." *Id.* at 1897. Dow's oral representations therefore greatly exceeded the "praise" offered on its label. Accordingly, holding Dow liable for those oral representations in no way would be "in addition to or different from" any labeling "requirements."

Cipollone held was not preempted, which alleged that cigarette manufacturers "possessed[] but had ignored and failed to act upon medical[] and scientific data indicating that cigarettes were hazardous to the health of consumers." *Id.* at 510 (internal quotation marks omitted). *See also Nelson v. Najm*, 127 S.W.3d 170, 175-76 (Tex. App. 2003) (warranty or "as is" provision invalid to negate fraud claim based on concealment of "a known fact").[34]

4. The negligence claims are not preempted

The farmers assert claims for negligence in the "development, testing, manufacture, production and promotion of Strongarm." JA 185. Because their theories concern the formulation and promotion of Strongarm, there is no conflicting FIFRA requirement. The Fifth Circuit's rationale for holding this claim preempted was that it is "simply a disguised claim for failure to warn." Pet. App. 19a. But because Dow's inducement to change its label can address only one theory for negligence – a breach of duty to promote accurately its products – there is no basis for preempting the farmers' claims for negligent testing, development, and manufacture of Strongarm as imposing a requirement in addition to or different from the label. *See, e.g., Quest Chem. Corp. v. Elam*, 898 S.W.2d 819, 820-21 (Tex. 1995) (per curiam) (noting that claims against pesticide manufacturer for negligent testing, manufacturing, and formulating should "escape FIFRA preemption" under Texas law because those claims are not based on

[34] Although Dow claimed below that the label's limitation of remedies provision would in any case limit recovery to replacement of the product or refund of the purchase price, it is black-letter law that public policy prevents a manufacturer from limiting its liability for its own fraud. *See Helena Chem. Co. v. Wilkins*, 47 S.W.3d 486, 505 (Tex. 2001) ("Helena's liability-limitation clauses cannot preclude the Wilkinses' lost-profit recovery for nonwarranty representations or unconscionability."); *Western Union Tel. Co. v. Edsall*, 63 Tex. 668, 1885 WL 7106, at *5 (1885) (enforcing limitation of liability clause on back of telegraph form only "in the absence of fraud").

"alleged failure to provide adequate warnings and instructions" on the label).

Moreover, as with the strict liability claims, because Dow admits that Strongarm is *never* safe to use in soils with a pH of 7.2 or greater, the negligence claims cannot be negated by a defense of inadequate warning that, when followed, would make the product safe for use. *See Cipollone*, 505 U.S. at 524-25 (plurality op.) (no preemption of "claims that rely solely on [maker's] testing or research practices or other actions unrelated to advertising or promotion"). And, because § 136v(a) empowers States directly to restrict pesticide sale or use, a damages suit that indirectly does so should not be preempted even if it might induce a label alteration. Section 136v(b) should not be read to undercut a State's express authority under § 136v(a), especially in areas traditionally regulated by States such as agriculture and consumer protection.

This is a classic case of inadequate testing, as evidenced by Dow's subsequent amendment to its Strongarm label to provide special instructions for use (or to prohibit use altogether) in Texas, New Mexico, and Oklahoma. Dow's theory of FIFRA would allow it to use the unfortunate farmers – to whom Dow marketed its new product directly with great fanfare at the Field Days – to perform its field testing, with little if any responsibility for the devastating consequences (including, for some, bankruptcy). The contrary decision of the court below creates a classic Catch 22. The label says on its face that it is "registered" with EPA and that its "approved uses" include "all areas where peanuts are grown." JA 107-08, 175. Thus, a farmer reasonably must rely on the EPA-approved pesticide label to obtain the product because without EPA approval the product cannot be sold. But, if he relies on the label's assurance that the product will work, then the law tells him, in effect, that he was crazy to have done so.

III. CLAIMS CHALLENGING POST-USE, OFF-LABEL STATEMENTS ARE NOT PREEMPTED

A last set of claims concerns representations by Dow after Strongarm had been used. *See* JA 190-91. Specifically, the farmers alleged that Dow had committed fraud, fraudulent inducement to contract, and breach of express warranty by promising to compensate the farmers for any damages they sustained from using Strongarm. They also contended that those post-use statements estopped Dow from claiming label defenses. *See id.* The Fifth Circuit erred in holding that the farmers' claims stemming from Dow's post-use representations are preempted. Pet. App. 16a-17a, 20a (fraud claims preempted).

The district court found that "FIFRA does not preempt these claims" because the "off-label remarks do not repeat any information found on the Strongarm label." Pet. App. 29a; *cf. Cipollone*, 505 U.S. at 525-26 (plurality op.) (If "a manufacturer expressly promised to pay a smoker's medical bills if she contracted emphysema, the duty to honor that promise could not fairly be said to be 'imposed under state law,' but rather is best understood as undertaken by the manufacturer itself.").[35] That conclusion was plainly correct, but the Fifth Circuit's overbroad opinion holds that "the farmers' claims for breach of warranty, fraud, DTPA, defective design and negligence are *all* preempted."

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[35] The district court subsequently has treated the court of appeals' judgment as affirming the dismissal of *all* of petitioners' claims on preemption grounds. Over the farmers' objection, the court returned all funds paid into the court's registry by Dow for damages resulting from, *inter alia*, its post-use representations, on the basis that petitioners had no more live claims for which a deposit would be warranted. *See* JA 226-27. This Court therefore should hold that the farmers' post-use claims also are not preempted, and permit the parties to litigate what effect, if any, the label's limitation of remedies provision has on those claims. The Fifth Circuit's suggestion that the farmers did not seek appellate review of the district court's determination on that point, *see* Pet. App. 17a n.15, is plainly contradicted by the farmers' opening brief below. *See* Appellants' Br. 51-55; Appellee's Br. 57-62; *see also supra* n.34 (purported limitation of liability for fraud is void).

Pet. App. 20a (emphasis added). The court based that view on the ground that "success on such claims would necessarily induce Dow to alter its product label." *Id.*

The court's holding is clearly erroneous. The farmers had used Strongarm and were relying on post-use representations that Dow would remedy their injuries from that use. Such theories of fraud, fraud in the inducement, warranty, estoppel, and waiver have nothing to do with the label. Whether Dow experiences any "induce[ment]" to change the label as a result of its post-use representations to the farmers stems not from any FIFRA requirements – which are completely silent on the question of what a manufacturer's legal responsibilities are to its consumers once its product is used – but rather from the self-interest of the manufacturer. This Court has never sanctioned preemption on the theory that a private-party manufacturer can exonerate itself from common-law liability by its voluntary actions not compelled by federal law.

CONCLUSION

The court of appeals' judgment should be reversed.

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7 U.S.C. § 136. Definitions

For purposes of this subchapter –

* * * * *

(p) Label and labeling

(1) Label

The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

(2) Labeling

The term "labeling" means all labels and all other written, printed, or graphic matter–

(A) accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

(q) Misbranded

(1) A pesticide is misbranded if–

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;

(C) it is an imitation of, or is offered for sale under the name of, another pesticide;

(D) its label does not bear the registration number assigned under section 136e of this title to each establishment in which it was produced;

(E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment; or

(H) in the case of a pesticide not registered in accordance with section 136a of this title and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: "Not Registered for Use in the United States of America".

(2) A pesticide is misbranded if–

(A) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retail package, if

there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions or purchase, except that a pesticide is not misbranded under this subparagraph if–

(i) The size or form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and

(ii) the ingredient statement appears prominently on another part of the immediate container, or outside container or wrapper, permitted by the Administrator;

(B) the labeling does not contain a statement of the use classification under which the product is registered;

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing–

(i) the name and address of the producer, registrant, or person for whom produced;

(ii) the name, brand, or trademark under which the pesticide is sold;

(iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and

(iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification; and

(D) the pesticide contains any substance or substances in quantities highly toxic to man, unless the label shall bear, in addition to any other matter required by this subchapter–

(i) the skull and crossbones;

(ii) the word "poison" prominently in red on a background of distinctly contrasting color; and

(iii) a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide.

* * * * *

7 U.S.C. § 136a. Registration of Pesticides

(a) Requirement of registration

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

(b) Exemptions

A pesticide which is not registered with the Administrator may be transferred if–

(1) the transfer is from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment; or

(2) the transfer is pursuant to and in accordance with the requirements of an experimental use permit.

(c) Procedure for registration

(1) Statement required

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes–

(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

(B) the name of the pesticide;

(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

(D) the complete formula of the pesticide;

(E) a request that the pesticide be classified for general use or for restricted use, or for both; and

(F) except as otherwise provided in paragraph (2)(D), if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) With respect to pesticides containing active ingredients that are initially registered under this subchapter after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide, except that such permission shall not be required in the case of defensive data.

(ii) The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after August 3, 1996, and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that–

(I) there are insufficient efficacious alternative registered pesticides available for the use;

(II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;

(III) the minor use pesticide plays or will play a significant part in managing pest resistance; or

(IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The registration of a pesticide for a minor use on a crop grouping established by the Administrator shall be considered for purposes of this clause 1 minor use for each representative crop for which data are provided in the crop grouping. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from the registration the minor uses which formed the basis for the extension of the additional exclusive use period or if the Administrator determines that the registrant is not actually marketing the product for such minor uses.

(iii) Except as otherwise provided in clause (i), with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of de-

livery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the

application. Notwithstanding any other provision of this subchapter, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation.

(iv) After expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under clauses (i), (ii), and (iii), the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data.

(v) The period of exclusive use provided under clause (ii) shall not take effect until 1 year after August 3, 1996, except where an applicant or registrant is applying for the registration of a pesticide containing an active ingredient not previously registered.

(vi) With respect to data submitted after August 3, 1996, by an applicant or registrant to support an amendment adding a new use to an existing registration that does not retain any period of exclusive use, if such data relates solely to a minor use of a pesticide, such data shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application for a minor use by another person during the period of 10 years following the date of submission of such data. The applicant or registrant at the time the new minor use is requested shall notify the Administrator that to the best of their knowledge the exclusive use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide is eligible for the provisions of this paragraph. If the minor use registration which is supported by data submitted pursuant to this subsection is voluntarily canceled or if such data are subsequently used to support a nonminor use, the data shall no longer be subject to the exclusive use provisions of this clause but shall instead be considered by the Administrator in accordance with the provisions of clause (i), as appropriate.

(G) If the applicant is requesting that the registration or amendment to the registration of a pesticide be expedited, an explanation of the basis for the request must be submitted, in accordance with paragraph (10) of this subsection.

(2) Data in support of registration

(A) In general

The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter the Administrator requires any additional kind of information under subparagraph (B) of this paragraph,

the Administrator shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, the public health and agricultural need for such minor use, and the level and degree of potential beneficial or adverse effects on man and the environment. The Administrator shall not require a person to submit, in relation to a registration or reregistration of a pesticide for minor agricultural use under this subchapter, any field residue data from a geographic area where the pesticide will not be registered for such use. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 136h of this title, within 30 days after the Administrator registers a pesticide under this subchapter the Administrator shall make available to the public the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to the Administrator's decision.

(B) Additional data

(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure

the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification. Any registrant who agrees to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iii) If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing, data, the registrants have not further agreed on the terms of the data development arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance

with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iv) Notwithstanding any other provision of this subchapter, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 136d(d) of this title. The only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is con-

sistent with this subchapter. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this subchapter, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(v) Any data submitted under this subparagraph shall be subject to the provisions of paragraph (1)(D). Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for the joint submitters of such data.

(vi) Upon the request of a registrant the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under section 136a-1 of this title for the other uses of the pesticide established as of August 3, 1996, if–

(I) the data to support other uses of the pesticide on a food are being provided;

(II) the registrant, in submitting a request for such an extension, provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(III) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under section 136a-1 of this title; and

(IV) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this clause, the Administrator may take action to modify or revoke the extension under this clause if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide, in writing to the registrant, a notice revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date established by the Administrator for the submission of the data.

(vii) If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the regis-

trant, shall not take any action pursuant to this clause in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under section 136a-1 of this title for the supported uses identified pursuant to this clause unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of this subparagraph regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding the provisions of this clause, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish

a new effective date by which the minor use shall be deleted from the registration.

(viii)(I) If data required to support registration of a pesticide under subparagraph (A) is requested by a Federal or State regulatory authority, the Administrator shall, to the extent practicable, coordinate data requirements, test protocols, timetables, and standards of review and reduce burdens and redundancy caused to the registrant by multiple requirements on the registrant.

(II) The Administrator may enter into a cooperative agreement with a State to carry out subclause (I).

(III) Not later than 1 year after August 3, 1996, the Administrator shall develop a process to identify and assist in alleviating future disparities between Federal and State data requirements.

(C) Simplified procedures

Within nine months after September 30, 1978, the Administrator shall, by regulation, prescribe simplified procedures for the registration of pesticides, which shall include the provisions of subparagraph (D) of this paragraph.

(D) Exemption

No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to–

(i) submit or cite data pertaining to such purchased product; or

(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

(E) Minor use waiver

In handling the registration of a pesticide for a minor use, the Administrator may waive otherwise applicable data requirements if the Administrator determines that the absence of such data will not prevent the Administrator from determining–

(i) the incremental risk presented by the minor use of the pesticide; and

(ii) that such risk, if any, would not be an unreasonable adverse effect on the environment.

(3) Time for acting with respect to application

(A) In general

The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance with paragraph (5), or notify the applicant of the Administrator's determination that it does not comply with the provisions of the subchapter in accordance with paragraph (6).

(B) Identical or substantially similar

(i) The Administrator shall, as expeditiously as possible, review and act on any application received by the Administrator that–

(I) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; or

(II) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data.

(ii) In expediting the review of an application for an action described in clause (i), the Administrator shall–

(I) within 45 days after receiving the application, notify the registrant whether or not the application is complete and, if the application is found to be incomplete, reject the application;

(II) within 90 days after receiving a complete application, notify the registrant if the application has been granted or denied; and

(III) if the application is denied, notify the registrant in writing of the specific reasons for the denial of the application.

(C) Minor use registration

(i) The Administrator shall, as expeditiously as possible, review and act on any complete application–

(I) that proposes the initial registration of a new pesticide active ingredient if the active ingredient is proposed to be registered solely for minor uses, or proposes a registration amendment solely for minor uses to an existing registration; or

(II) for a registration or a registration amendment that proposes significant minor uses.

(ii) For the purposes of clause (i)–

(I) the term "as expeditiously as possible" means that the Administrator shall, to the greatest extent practicable, complete a review and evaluation of all data, submitted with a complete application, within 12 months after the submission of the complete application, and the failure of the Administrator to complete such a review and evaluation under clause (i) shall not be subject to judicial review; and

(II) the term "significant minor uses" means 3 or more minor uses proposed for every nonminor use, a minor use that would, in the judgment of the Ad-

ministrator, serve as a replacement for any use which has been canceled in the 5 years preceding the receipt of the application, or a minor use that in the opinion of the Administrator would avoid the reissuance of an emergency exemption under section 136p of this title for that minor use.

(D) Adequate time for submission of minor use data

If a registrant makes a request for a minor use waiver, regarding data required by the Administrator, pursuant to paragraph (2)(E), and if the Administrator denies in whole or in part such data waiver request, the registrant shall have a full-time period for providing such data. For purposes of this subparagraph, the term "full-time period" means the time period originally established by the Administrator for submission of such data, beginning with the date of receipt by the registrant of the Administrator's notice of denial.

(4) Notice of application

The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment.

(5) Approval of registration

The Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed under subsection (d) of this section–

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this subchapter;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 136v(c) of this title, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

(6) Denial of registration

If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, the Administrator shall notify the applicant for registration of the Administrator's determination and of the Administrator's reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide. Whenever the Administrator refuses to register a pesticide, the Administrator shall notify the applicant of the Administrator's decision and of the Administrator's rea-

sons (including the factual basis) therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 136d of this title.

(7) Registration under special circumstances

Notwithstanding the provisions of paragraph (5)–

(A) The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. An applicant seeking conditional registration or amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data because it has not yet been generated, the Administrator may register or amend the registration of the pesticide under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

(B) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. Notwithstanding the foregoing provisions of this subparagraph, no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure enumerated in regulations issued under this subchapter, and during the pendency of any risk-benefit evaluation initiated by such notice, if (I) the additional use of such pesticide involves a major food or feed crop, or (II) the additional use of such pesticide involves a minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria. An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

(C) The Administrator may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and

submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this subchapter, and on such other conditions as the Administrator may prescribe. A conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

(8) Interim administrative review

Notwithstanding any other provision of this subchapter, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this subchapter, unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment. Notice of the definition of the terms "validated test" and "other significant evidence" as used herein shall be published by the Administrator in the Federal Register.

(9) Labeling

(A) Additional statements

Subject to subparagraphs (B) and (C), it shall not be a violation of this subchapter for a registrant to modify the labeling of an antimicrobial pesticide product to include relevant information on product efficacy, product composition, container composition or

design, or other characteristics that do not relate to any pesticidal claim or pesticidal activity.

(B) Requirements

Proposed labeling information under subparagraph (A) shall not be false or misleading, shall not conflict with or detract from any statement required by law or the Administrator as a condition of registration, and shall be substantiated on the request of the Administrator.

(C) Notification and disapproval

(i) Notification

A registration may be modified under subparagraph (A) if–

(I) the registrant notifies the Administrator in writing not later than 60 days prior to distribution or sale of a product bearing the modified labeling; and

(II) the Administrator does not disapprove of them modification under clause (ii).

(ii) Disapproval

Not later than 30 days after receipt of a notification under clause (i), the Administrator may disapprove the modification by sending the registrant notification in writing stating that the proposed language is not acceptable and stating the reasons why the Administrator finds the proposed modification unacceptable.

(iii) Restriction on sale

A registrant may not sell or distribute a product bearing a disapproved modification.

(iv) Objection

A registrant may file an objection in writing to a disapproval under clause (ii) not later than 30 days after receipt of notification of the disapproval.

(v) Final action

A decision by the Administrator following receipt and consideration of an objection filed under clause (iv) shall be considered a final agency action.

(D) Use dilution

The label or labeling required under this subchapter for an antimicrobial pesticide that is or may be diluted for use may have a different statement of caution or protective measures for use of the recommended diluted solution of the pesticide than for use of a concentrate of the pesticide if the Administrator determines that–

(i) adequate data have been submitted to support the statement proposed for the diluted solution uses; and

(ii) the label or labeling provides adequate protection for exposure to the diluted solution of the pesticide.

(10) Expedited registration of pesticides

(A) Not later than 1 year after August 3, 1996, the Administrator shall, utilizing public comment, develop procedures and guidelines, and expedite the review of an application for registration of a pesticide or an amendment to a registration that satisfies such guidelines.

(B) Any application for registration or an amendment, including biological and conventional pesticides, will be considered for expedited review under this paragraph. An application for registration or an amendment shall qualify for expedited review if use of the pesticide proposed by the application may reasonably be expected to accomplish 1 or more of the following:

(i) Reduce the risks of pesticides to human health.

(ii) Reduce the risks of pesticides to nontarget organisms.

(iii) Reduce the potential for contamination of groundwater, surface water, or other valued environmental resources.

(iv) Broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective.

(C) The Administrator, not later than 30 days after receipt of an application for expedited review, shall notify the applicant whether the application is complete. If it is found to be incomplete, the Administrator may either reject the request for expedited review or ask the applicant for additional information to satisfy the guidelines developed under subparagraph (A).

(d) Classification of pesticides

(1) Classification for general use, restricted use, or both

(A) As a part of the registration of a pesticide the Administrator shall classify it as being for general use or for restricted use. If the Administrator determines that some of the uses for which the pesticide is registered should be for general use and that other uses for which it is registered should be for restricted use, the Administrator shall classify it for both general use and restricted use. Pesticide uses may be classified by regulation on the initial classification, and registered pesticides may be classified prior to reregistration. If some of the uses of the pesticide are classified for general use, and other uses are classified for restricted use, the directions relating to its general uses shall be clearly separated and distinguished from those directions relating to its restricted uses. The Administrator may require that its packaging and labeling for restricted uses shall be clearly

distinguishable from its packaging and labeling for general uses.

(B) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment, the Administrator will classify the pesticide, or the particular use or uses of the pesticide to which the determination applies, for general use.

(C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, the Administrator shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted use:

(i) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied for any use to which the restricted classification applies only by or under the direct supervision of a certified applicator.

(ii) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation. Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.

(2) Change in classification

If the Administrator determines that a change in the classification of any use of a pesticide from general use to restricted use is necessary to prevent unreasonable adverse effects on the environment, the Administrator shall notify the registrant of such pesticide of such determination at least forty-five days before making the change and shall publish the proposed change in the Federal Register. The registrant, or other interested person with the concurrence of the registrant, may seek relief from such determination under section 136d(b) of this title.

(3) Change in classification from restricted use to General use

The registrant of any pesticide with one or more uses classified for restricted use may petition the Administrator to change any such classification from restricted to general use. Such petition shall set out the basis for the registrant's position that restricted use classification is unnecessary because classification of the pesticide for general use would not cause unreasonable adverse effects on the environment. The Administrator, within sixty days after receiving such petition, shall notify the registrant whether the petition has been granted or denied. Any denial shall contain an explanation therefor and any such denial shall be subject to judicial review under section 136n of this title.

(e) Products with same formulation and claims

Products which have the same formulation, are manufactured by the same person, the labeling of which contains the same claims, and the labels of which bear a designation identifying the product as the same pesticide may be registered as a single pesticide; and additional names and labels shall be added to the registration by supplemental statements.

(f) Miscellaneous

(1) Effect of change of labeling or formulation

If the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this subchapter.

(2) Registration not a defense

In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter.

(3) Authority to consult other Federal agencies

In connection with consideration of any registration or application for registration under this section, the Administrator may consult with any other Federal agency.

(4) Mixtures of nitrogen stabilizers and fertilizer products

Any mixture or other combination of–

(A) 1 or more nitrogen stabilizers registered under this subchapter; and

(B) 1 or more fertilizer products,

shall not be subject to the provisions of this section or sections 136a-1, 136c, 136e, 136m, and 136o(a)(2) of this title if the mixture or other combination is accompanied by the labeling required under this subchapter for the nitrogen stabilizer contained in the mixture or other combination, the mixture or combination is mixed or combined in accordance with such labeling, and the mixture or combination does not contain any active ingredient other than the nitrogen stabilizer.

(g) Registration review

(1) General rule

(A) Periodic review

The registrations of pesticides are to be periodically reviewed. The Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations. The goal of these regulations shall be a review of a pesticide's registration every 15 years. No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 136d of this title.

(B) Limitation

Nothing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide pursuant to this subchapter.

(2) Data

(A) Submission required

The Administrator shall use the authority in subsection (c)(2)(B) of this section to require the submission of data when such data are necessary for a registration review.

(B) Data submission, compensation, and exemption

For purposes of this subsection, the provisions of subsections (c)(1), (c)(2)(B), and (c)(2)(D) of this sec-

tion shall be utilized for and be applicable to any data required for registration review.

(h) Registration requirements for antimicrobial pesticides

(1) Evaluation of process

To the maximum extent practicable consistent with the degrees of risk presented by an antimicrobial pesticide and the type of review appropriate to evaluate the risks, the Administrator shall identify and evaluate reforms to the antimicrobial registration process that would reduce review periods existing as of August 3, 1996, for antimicrobial pesticide product registration applications and applications for amended registration of antimicrobial pesticide products, including–

(A) new antimicrobial active ingredients;

(B) new antimicrobial end-use products;

(C) substantially similar or identical antimicrobial pesticides; and

(D) amendments to antimicrobial pesticide registrations.

(2) Review time period reduction goal

Each reform identified under paragraph (1) shall be designed to achieve the goal of reducing the review period following submission of a complete application, consistent with the degree of risk, to a period of not more than–

(A) 540 days for a new antimicrobial active ingredient pesticide registration;

(B) 270 days for a new antimicrobial use of a registered active ingredient;

(C) 120 days for any other new antimicrobial product;

(D) 90 days for a substantially similar or identical antimicrobial product;

(E) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(F) 90 to 180 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this paragraph.

(3) Implementation

(A) Proposed rulemaking

(i) Issuance

Not later than 270 days after August 3, 1996, the Administrator shall publish in the Federal Register proposed regulations to accelerate and improve the review of antimicrobial pesticide products designed to implement, to the extent practicable, the goals set forth in paragraph (2).

(ii) Requirements

Proposed regulations issued under clause (i) shall–

(I) define the various classes of antimicrobial use patterns, including household, industrial, and institutional disinfectants and sanitizing pesticides, preservatives, water treatment, and pulp and paper mill additives, and other such products intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms, or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime;

(II) differentiate the types of review undertaken for antimicrobial pesticides;

(III) conform the degree and type of review to the risks and benefits presented by antimicrobial pesticides and the function of review under this subchapter, considering the use patterns of the product, toxicity, expected exposure, and product type;

(IV) ensure that the registration process is sufficient to maintain antimicrobial pesticide efficacy and that antimicrobial pesticide products continue to meet product performance standards and effectiveness levels for each type of label claim made; and

(V) implement effective and reliable deadlines for process management.

(iii) Comments

In developing the proposed regulations, the Administrator shall solicit the views from registrants and other affected parties to maximize the effectiveness of the rule development process.

(B) Final regulations

(i) Issuance

The Administrator shall issue final regulations not later than 240 days after the close of the comment period for the proposed regulations.

(ii) Failure to meet goal

If a goal described in paragraph (2) is not met by the final regulations, the Administrator shall identify the goal, explain why the goal was not attained, describe the element of the regulations included instead, and identify future steps to attain the goal.

(iii) Requirements

In issuing final regulations, the Administrator shall–

(I) consider the establishment of a certification process for regulatory actions involving risks that can be responsibly managed, consistent with the degree of risk, in the most cost-efficient manner;

(II) consider the establishment of a certification process by approved laboratories as an adjunct to the review process;

(III) use all appropriate and cost-effective review mechanisms, including–

(aa) expanded use of notification and non-notification procedures;

(bb) revised procedures for application review; and

(cc) allocation of appropriate resources to ensure streamlined management of antimicrobial pesticide registrations; and

(IV) clarify criteria for determination of the completeness of an application.

(C) Expedited review

This subsection does not affect the requirements or extend the deadlines or review periods contained in subsection (c)(3) of this section.

(D) Alternative review periods

If the final regulations to carry out this paragraph are not effective 630 days after August 3, 1996, until the final regulations become effective, the review period, beginning on the date of receipt by the Agency of a complete application, shall be–

(i) 2 years for a new antimicrobial active ingredient pesticide registration;

(ii) 1 year for a new antimicrobial use of a registered active ingredient;

(iii) 180 days for any other new antimicrobial product;

(iv) 90 days for a substantially similar or identical antimicrobial product;

(v) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(vi) 240 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this subparagraph.

(E) Wood preservatives

An application for the registration, or for an amendment to the registration, of a wood preservative product for which a claim of pesticidal activity listed in section 136(mm) of this title is made (regardless of any other pesticidal claim that is made with respect to the product) shall be reviewed by the Administrator within the same period as that established under this paragraph for an antimicrobial pesticide product application, consistent with the degree of risk posed by the use of the wood preservative product, if the application requires the applicant to satisfy the same data requirements as are required to support an application for a wood preservative product that is an antimicrobial pesticide.

(F) Notification

(i) In general

Subject to clause (iii), the Administrator shall notify an applicant whether an application has been granted or denied not later than the final day of the appropriate review period under this paragraph, unless the applicant and the Administrator agree to a later date.

(ii) Final decision

If the Administrator fails to notify an applicant within the period of time required under clause (i), the failure shall be considered an agency action unlawfully withheld or unreasonably delayed for purposes of judicial review under chapter 7 of title 5.

(iii) Exemption

This subparagraph does not apply to an application for an antimicrobial pesticide that is filed under subsection (c)(3)(B) of this section prior to 90 days after August 3, 1996.

(4) Annual report

(A) Submission

Beginning on August 3, 1996, and ending on the date that the goals under paragraph (2) are achieved, the Administrator shall, not later than March 1 of each year, prepare and submit an annual report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

(B) Requirements

A report submitted under subparagraph (A) shall include a description of–

(i) measures taken to reduce the backlog of pending registration applications;

(ii) progress toward achieving reforms under this subsection; and

(iii) recommendations to improve the activities of the Agency pertaining to antimicrobial registrations.

7 U.S.C. § 136j. Unlawful acts

(a) In general

(1) Except as provided by subsection (b) of this section, it shall be unlawful for any person in any State to distribute or sell to any person –

(A) any pesticide that is not registered under section 136a of this title or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this subchapter;

(B) any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 136a of this title;

(C) any registered pesticide the composition of which differs at the time of its distribution or sale from its composition as described in the statement required in connection with its registration under section 136a of this title;

(D) any pesticide which has not been colored or discolored pursuant to the provisions of section 136w(c)(5) of this title;

(E) any pesticide which is adulterated or misbranded; or

(F) any device which is misbranded.

(2) It shall be unlawful for any person –

(A) to detach, alter, deface, or destroy, in whole or in part, any labeling required under this subchapter;

(B) to refuse to –

(i) prepare, maintain, or submit any records required by or under section 136c, 136e, 136f, 136i, or 136q of this title;

(ii) submit any reports required by or under section 136c, 136d, 136e, 136f, 136i, or 136q of this title; or

(iii) allow any entry, inspection, copying of records, or sampling authorized by this subchapter;

(C) to give a guaranty or undertaking provided for in subsection (b) of this section which is false in any particular, except that a person who receives and relies upon a guaranty authorized under subsection (b) of this section may give a guaranty to the same effect, which guaranty shall contain, in addition to the person's own name and address, the name and address of the person residing in the United States from whom the person received the guaranty or undertaking;

(D) to use for the person's own advantage or to reveal, other than to the Administrator, or officials or employees of the Environmental Protection Agency or other Federal executive agencies, or to the courts, or to physicians, pharmacists, and other qualified persons, needing such information for the performance of their duties, in accordance with such directions as the Administrator may prescribe, any information acquired by authority of this subchapter which is confidential under this subchapter;

(E) who is a registrant, wholesaler, dealer, retailer, or other distributor to advertise a product registered under this subchapter for restricted use without giving the classification of the product assigned to it under section 136a of this title;

(F) to distribute or sell, or to make available for use, or to use, any registered pesticide classified for restricted use for some or all purposes other than in accordance with section 136a(d) of this title and any regulations thereunder, except that it shall not be unlawful to sell, under regulations issued by the Administrator, a restricted use pesticide to a person who

is not a certified applicator for application by a certified applicator;

(G) to use any registered pesticide in a manner inconsistent with its labeling;

(H) to use any pesticide which is under an experimental use permit contrary to the provisions of such permit;

(I) to violate any order issued under section 136k of this title;

(J) to violate any suspension order issued under section 136a(c)(2)(B), 136a-1, or 136d of this title;

(K) to violate any cancellation order issued under this subchapter or to fail to submit a notice in accordance with section 136d(g) of this title;

(L) who is a producer to violate any of the provisions of section 136e of this title;

(M) to knowingly falsify all or part of any application for registration, application for experimental use permit, any information submitted to the Administrator pursuant to section 136e of this title, any records required to be maintained pursuant to this subchapter, any report filed under this subchapter, or any information marked as confidential and submitted to the Administrator under any provision of this subchapter;

(N) who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by this subchapter;

(O) to add any substance to, or take any substance from, any pesticide in a manner that may defeat the purpose of this subchapter;

(P) to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasona-

bly foreseeable therefrom, and (ii) freely volunteer to participate in the test;

(Q) to falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed, submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by this subchapter;

(R) to submit to the Administrator data known to be false in support of a registration; or

(S) to violate any regulation issued under section 136a(a) or 136q of this title.

(b) Exemptions

The penalties provided for a violation of paragraph (1) of subsection (a) of this section shall not apply to –

(1) any person who establishes a guaranty signed by, and containing the name and address of, the registrant or person residing in the United States from whom the person purchased or received in good faith the pesticide in the same unbroken package, to the effect that the pesticide was lawfully registered at the time of sale and delivery to the person, and that it complies with the other requirements of this subchapter, and in such case the guarantor shall be subject to the penalties which would otherwise attach to the person holding the guaranty under the provisions of this subchapter;

(2) any carrier while lawfully shipping, transporting, or delivering for shipment any pesticide or device, if such carrier upon request of any officer or employee duly designated by the Administrator shall permit such officer or employee to copy all of its records concerning such pesticide or device;

(3) any public official while engaged in the performance of the official duties of the public official;

(4) any person using or possessing any pesticide as provided by an experimental use permit in effect with respect to such pesticide and such use or possession; or

(5) any person who ships a substance or mixture of substances being put through tests in which the purpose is only to determine its value for pesticide purposes or to determine its toxicity or other properties and from which the user does not expect to receive any benefit in pest control from its use.

7 U.S.C. § 136v. Authority of States

(a) In general

A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

(b) Uniformity

Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

(c) Additional uses

(1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this subchapter and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator. Such registration shall be deemed registration under section 136a of this title for all purposes of this subchapter, but shall authorize distribution and use only within such State.

(2) A registration issued by a State under this subsection shall not be effective for more than ninety days if disapproved by the Administrator within that period. Prior to disapproval, the Administrator shall, except as provided in paragraph (3) of this subsection, advise the State of the Administrator's intention to disapprove and the reasons therefor, and provide the State time to respond. The Administrator shall not prohibit or disapprove a registration issued by a State under this subsection (A) on the basis of lack of essentiality of a pesticide or (B) except as provided in paragraph (3) of this subsection, if its composition and use patterns are similar to those of a federally registered pesticide.

(3) In no instance may a State issue a registration for a food or feed use unless there exists a tolerance or ex-

emption under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) that permits the residues of the pesticides on the food or feed. If the Administrator determines that a registration issued by a State is inconsistent with the Federal Food, Drug, and Cosmetic Act, or the use of, a pesticide under a registration issued by a State constitutes an imminent hazard, the Administrator may immediately disapprove the registration.

(4) If the Administrator finds, in accordance with standards set forth in regulations issued under section 136w of this title, that a State is not capable of exercising adequate controls to assure that State registration under this section will be in accord with the purposes of this subchapter or has failed to exercise adequate controls, the Administrator may suspend the authority of the State to register pesticides until such time as the Administrator is satisfied that the State can and will exercise adequate controls. Prior to any such suspension, the Administrator shall advise the State of the Administrator's intention to suspend and the reasons therefor and provide the State time to respond.

7 U.S.C. § 136w-1. State primary enforcement responsibility

(a) In general

For the purposes of this subchapter, a State shall have primary enforcement responsibility for pesticide use violations during any period for which the Administrator determines that such State –

(1) has adopted adequate pesticide use laws and regulations, except that the Administrator may not require a State to have pesticide use laws that are more stringent than this subchapter;

(2) has adopted and is implementing adequate procedures for the enforcement of such State laws and regulations; and

(3) will keep such records and make such reports showing compliance with paragraphs (1) and (2) of this subsection as the Administrator may require by regulation.

(b) Special rules

Notwithstanding the provisions of subsection (a) of this section, any State that enters into a cooperative agreement with the Administrator under section 136u of this title for the enforcement of pesticide use restrictions shall have the primary enforcement responsibility for pesticide use violations. Any State that has a plan approved by the Administrator in accordance with the requirements of section 136i of this title that the Administrator determines meets the criteria set out in subsection (a) of this section shall have the primary enforcement responsibility for pesticide use violations. The Administrator shall make such determinations with respect to State plans under section 136i of this title in effect on September 30, 1978, not later than six months after that date.

(c) Administrator

The Administrator shall have primary enforcement responsibility for those States that do not have primary en-

forcement responsibility under this subchapter. Notwithstanding the provisions of section 136(e)(1) of this title, during any period when the Administrator has such enforcement responsibility, section 136f(b) of this title shall apply to the books and records of commercial applicators and to any applicator who holds or applies pesticides, or uses dilutions of pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and section 136g(a) of this title shall apply to the establishment or other place where pesticides or devices are held for application by such persons with respect to pesticides or devices held for such application.

7 U.S.C. § 136w-2. Failure by the State to assure enforcement of State

(a) Referral

Upon receipt of any complaint or other information alleging or indicating a significant violation of the pesticide use provisions of this subchapter, the Administrator shall refer the matter to the appropriate State officials for their investigation of the matter consistent with the requirements of this subchapter. If, within thirty days, the State has not commenced appropriate enforcement action, the Administrator may act upon the complaint or information to the extent authorized under this subchapter.

(b) Notice

Whenever the Administrator determines that a State having primary enforcement responsibility for pesticide use violations is not carrying out (or cannot carry out due to the lack of adequate legal authority) such responsibility, the Administrator shall notify the State. Such notice shall specify those aspects of the administration of the State program that are determined to be inadequate. The State shall have ninety days after receipt of the notice to correct any deficiencies. If after that time the Administrator determines that the State program remains inadequate, the Administrator may rescind, in whole or in part, the State's primary enforcement responsibility for pesticide use violations.

(c) Construction

Neither section 136w-1 of this title nor this section shall limit the authority of the Administrator to enforce this subchapter, where the Administrator determines that emergency conditions exist that require immediate action on the part of the Administrator and the State authority is unwilling or unable adequately to respond to the emergency.

7 U.S.C. § 136w-5. Minimum requirements for training of maintenance applicators and service technicians

Each State may establish minimum requirements for training of maintenance applicators and service technicians. Such training may include instruction in the safe and effective handling and use of pesticides in accordance with the Environmental Protection Agency approved labeling, and instruction in integrated pest management techniques. The authority of the Administrator with respect to minimum requirements for training of maintenance applicators and service technicians shall be limited to ensuring that each State understands the provisions of this section.

7 U.S.C. § 136a. Registration of Pesticides – (1976 ed.)

* * * * *

(c) Procedure for registration

* * * * *

(5) Approval of registration

The Administrator shall register a pesticide if he determines that, when considered with any restrictions imposed under subsection (d) –

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this subchapter;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other.

* * * * *

40 C.F.R. § 152.50. Contents of application.

Each application for registration or amended registration must include the following information, as applicable:

(a) *Application form.* An application form must be completed and submitted to the Agency. Application forms are provided by the Agency, with instructions as to the number of copies required and proper completion.

(b) *Identity of the applicant*–(1) *Name.* The applicant must identify himself. An applicant not residing in the United States must also designate an agent in accordance with paragraph (b)(3) of this section to act on behalf of the applicant on all registration matters.

(2) *Address of record.* The applicant must provide an address in the United States for correspondence purposes. The U.S. address provided will be considered the applicant's address of record, and EPA will send all correspondence concerning the application and any subsequent registration to that address. It is the responsibility of the applicant and any registrant under § 152.122 to ensure that the Agency has a current and accurate address.

(3) *Authorized agent.* An applicant may designate a person residing in the United States to act as his agent. If an applicant wishes to designate an agent, he must send the Agency a letter stating the name and United States address of his agent. The applicant must notify the Agency if he changes his designated agent. This relationship may be terminated at any time by the applicant by notifying the Agency in writing.

(4) *Company number.* If an applicant has been assigned a company number by the Agency, the application must reference that number.

(c) *Summary of the application.* Each application must include a list of the data submitted with the application, together with a brief description of the results of the studies. The list of data submitted may be the same as the list required by § 158.32 of this chapter. The summary must

state that is is [*sic*] releasable to the public after registration in accordance with § 152.119.

(d) *Identity of the product.* The product for which application is being submitted must be identified. The following information is required:

(1) The product name;

(2) The trade name(s) (if different); and

(3) The EPA Registration Number, if currently registered.

(e) *Draft labeling.* Each application for new registration must be accompanied by five legible copies of draft labeling (typescript or mock-up). Each application for amended registration that proposes to make any changes in the product labeling must be accompanied by five legible copies of draft labeling incorporating the proposed labeling changes. If the proposed labeling change affects only a portion of the labeling, such as the use directions, the applicant may submit five copies of that portion of the label which is the subject of the amendment. Upon request, an applicant for amended registration must submit a complete label to consolidate amendments.

(f) *Registration data requirements.* (1) An applicant must submit materials to demonstrate that he has complied with the FIFRA sec. 3(c)(1)(D) and subpart E of this part with respect to satisfaction of data requirements, to enable the Agency to make th determination required by FIFRA sec. 3(c)(5)(B). Required items are described in subpart E of this part.

(2) An applicant must furnish any data specified in part 158 of this chapter which are required by the Agency to determine that the product meets the registration standards of FIFRA sec. 3(c) (5) or (7). Each study must comply with:

(i) Section 158.30 of this chapter, with respect to times for submission;

(ii) Section 158.32 of this chapter, with respect to format of submission;

(iii) Section 158.33 of this chapter, with respect to studies for which a claim of trade secret or confidential business information is made;

(iv) Section 158.34 of this chapter, with respect to flagging for potential adverse effects; and

(v) Section 160.12 of this chapter, if applicable, with respect to a statement of whether studies were conducted in accordance with the Good Laboratory Practices of part 160.

(3) An applicant shall furnish with his application any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on man or the environment, which would be required to be reported under FIFRA sec. 6(a)(2) if the product were registered.

(g) *Certification relating to child-resistant packaging.* If the product meets the criteria for child-resistant packaging, the applicant must submit a certification that the product will be distributed or sold only in child-resistant packaging. Refer to part 157 of this chapter for the criteria and certification requirements.

(h) *Request for classification.* If an applicant wishes to request a classification different from that established by the Agency, he must submit a request for such classification and information supporting the request.

(i) *Statement concerning tolerances.* If the proposed labeling bears instructions for use of the pesticide on food or feed crops, or if the intended use of the pesticide results or may be expected to result, directly or indirectly, in pesticide residues in or on food or feed (including residues of any active ingredient, inert ingredient, metabolite, or degradation product), the applicant must submit a statement indicating whether such residues are authorized by a tolerance, exemption from the requirement of a tolerance, or food additive regulation issued under section 408 or 409 of

the Federal Food, Drug and Cosmetic Act (FFDCA). If such residues have not been authorized, the application must be accompanied by a petition for establishment of appropriate tolerances, exemptions from the requirement of a tolerance, or food additive regulations, in accordance with part 180 of this chapter.

40 C.F.R. § 152.112. Approval of registration under FIFRA sec. 3(c)(5).

EPA will approve an application under the criteria of FIFRA sec. 3(c)(5) only if:

(a) The Agency has determined that the application is complete and is accompanied by all materials required by the Act and this part, including, but not limited to, evidence of compliance with subpart E of this part;

(b) The Agency has reviewed all relevant data in the possession of the Agency (see §§ 152.107 and 152.111);

(c) The Agency has determined that no additional data are necessary to make the determinations required by FIFRA sec. 3(c)(5) with respect to the pesticide product which is the subject of the application;

(d) The Agency has determined that the composition of the product is such as to warrant the proposed efficacy claims for it, if efficacy data are required to be submitted by part 158 of this chapter for the product;

(e) The Agency has determined that the product will perform its intended function without unreasonable adverse effects on the environment, and that, when used in accordance with widespread and commonly recognized practice, the product will not generally cause unreasonable adverse effects on the environment;

(f) The Agency has determined that the product is not misbranded as that term is defined in FIFRA sec. 2(q) and part 156 of this chapter, and its labeling and packaging comply with the applicable requirements of the Act, this part, and parts 156 and 157 of this chapter;

(g) If the proposed labeling bears directions for use on food, animal feed, or food or feed crops, or if the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in pesticide residues (including residues of any active or inert ingredient of the product, or of any metabolite or degradation product thereof) in or on food or animal feed, all necessary tolerances, exemptions from the requirement of a tolerance, and food additive regulations have been issued under FFDCA sec. 408, sec. 409 or both; and

(h) If the product, in addition to being a pesticide, is a drug within the meaning of FFDCA sec. 201(q), the Agency has been notified by the Food and Drug Administration (FDA) that the product complies with any requirements imposed by FDA.

40 C.F.R. § 152.113. Approval of registration under FIFRA sec. 3(c)(7)—Products that do not contain a new active ingredient.

(a) Except as provided in paragraph (b) of this section, the Agency may approve an application for registration or amended registration of a pesticide product, each of whose active ingredients is contained in one or more other registered peticide [*sic*] products, only if the Agency has determined that:

(1) It possesses all data necessary to make the determinations required by FIFRA sec. 3(c)(7)(A) or (B) with respect to the pesticide product which is the subject of the application (including, at a minimum, data needed to characterize any incremental risk that would result from approval of the application);

(2) Approval of the application would not significantly increase the risk of any unreasonable adverse effect on the environment; and

(3) The criteria of § 152.112(a), (d), and (f) through (h) have been satisfied.

(b) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide under FIFRA sec. 3(c)(7)(A) unless the Agency has determined that the applicant's product and its proposed use are identical or substantially similar to a currently registered pesticide and use, or that the pesticide and its proposed use differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment.

(c) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide product for a new use under FIFRA sec. 3(c)(7)(B) if:

(1) The pesticide is the subject of a special review, based on a use of the product that results in human dietary exposure; and

(2) The proposed new use involves use on a major food or feed crop, or involves use on a minor food or feed crop for which there is available an effective alternative registered pesticide which does not meet the risk criteria associated with human dietary exposure. The determination of available and effective alternatives shall be made with the concurrence of the Secretary of Agriculture.

40 C.F.R. § 156.10. Labeling requirements.

(a) *General*–(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Hazard and precautionary statements as prescribed in subpart D of this part for human and domestic animal hazards and subpart E of this part for environmental hazards.

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such

terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*–(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*–(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to

the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling [*sic*], including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 152.500, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

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40 C.F.R. § 156.60. General.

Each product label is required to bear hazard and precautionary statements for humans and domestic animals (if applicable) as prescribed in this subpart. Hazard statements describe the type of hazard that may occur, while precautionary statements will either direct or inform the user of actions to take to avoid the hazard or mitigate its effects.

(a) *Location of statements*–(1) *Front panel statements.* The signal word, child hazard warning, and, in certain cases, the first aid statement are required to appear on the front panel of the label, and also in any supplemental labeling intended to accompany the product in distribution or sale.

(2) *Statements elsewhere on label.* Hazard and precautionary statements not required on the front panel may appear on other panels of the label, and may be required also in supplemental labeling. These include, but are not limited to, the human hazard and precautionary statements, domestic animal statements if applicable, a Note to Physician, and physical or chemical hazard statements.

(b) *Placement and prominence*–(1) *Front panel statements.* All required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The table below shows the minimum type size requirements for the front panel warning statements for various front panel sizes.

TYPE SIZES FOR FRONT PANEL WARNING STATEMENTS

Size of Label Front Panel (Square Inches)	Point Size: Signal Word (All Capital Letters)	Point Size: Child Hazard Warning
5 and under	6	6
Over 5 to 10	10	6
Over 10 to 15	12	8
Over 15 to 30	14	10
Over 30	18	12

(2) *Other required statements.* All other hazard and precautionary statements must be at least 6 point type.

40 C.F.R. § 156.62. Toxicity Category.

This section establishes four Toxicity Categories for acute hazards of pesticide products, Category I being the highest toxicity category. Most human hazard, precautionary statements, and human personal protective equipment statements are based upon the Toxicity Category of the pesticide product as sold or distributed. In addition, toxicity categories may be used for regulatory purposes other than labeling, such as classification for restricted use and requirements for child-resistant packaging. In certain cases, statements based upon the Toxicity Category of the product as diluted for use are also permitted. A Toxicity Category is assigned for each of five types of acute exposure, as specified in the table in this paragraph.

ACUTE TOXICITY CATEGORIES FOR PESTICIDE PRODUCTS

Hazard Indicators	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	>50 thru 500 mg/kg	>500 thru 5,000 mg/kg	>5,000 mg/kg
Dermal LD_{50}	Up to and including 200 mg/kg	>200 thru 2000 mg/kg	>2000 thru 20,000 mg/kg	>20,000 mg/kg
Inhalation LC_{50}	Up to and including 0.2 mg/liter	>0.2 thru 2 mg/liter	>2 thru 20 mg/liter	>20 mg/liter
Eye irritation	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin irritation	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

40 C.F.R. § 156.64. Signal word.

(a) *Requirement.* Except as provided in paragraph (a)(4), each pesticide product must bear on the front panel a signal word, reflecting the highest Toxicity Category (Category I is the highest toxicity category) to which the product is assigned by any of the five routes of exposure in § 156.62. The signal word must also appear together with the heading for the human precautionary statement section of the labeling (see § 156.70).

(1) *Toxicity Category I.* Any pesticide product meeting the criteria of Toxicity Category I for any route of exposure must bear on the front panel the signal word "DANGER." In addition, if the product is assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye irritation), the word "Poison" must appear in red on a background of distinctly contrasting color, and the skull and crossbones symbol must appear in immediate proximity to the word "Poison."

(2) *Toxicity Category II.* Any pesticide product meeting the criteria of Toxicity Category II as the highest category by any route of exposure must bear on the front panel the signal word "WARNING."

(3) *Toxicity Category III.* Any pesticide product meeting the criteria of Toxicity Category III as the highest category by any route of exposure must bear on the front panel the signal word "CAUTION."

(4) *Toxicity Category IV.* A pesticide product meeting the criteria of Toxicity Category IV by all routes of exposure is not required to bear a signal word. If a signal word is used, it must be "CAUTION."

(b) *Use of signal words.* In no case may a product:

(1) Bear a signal word reflecting a higher Toxicity Category than indicated by the route of exposure of highest toxicity, unless the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment;

(2) Bear a signal word reflecting a lesser Toxicity Category associated with a diluted product. Although precautionary statements for use dilutions may be included on label, the signal word must reflect the toxicity of the product as distributed or sold; or

(3) Bear different signal words on different parts of the label.

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40 C.F.R. § 156.66. Child hazard warning.

(a) Each pesticide product must bear on the front panel of the label the statement "Keep Out of Reach of Children." That statement, or any alternative statement approved by EPA, must appear on a separate line in close proximity to the signal word, if required. The statement is required on Toxicity Category IV products that do not otherwise require a signal word.

(b) In its discretion, EPA may waive the requirement, or require or permit an alternative child hazard warning, if:

(1) The applicant can demonstrate that the likelihood of exposure of children to the pesticide during distribution, marketing, storage or use is remote (for example, an industrial use product); or

(2) The pesticide is approved for use on children (for example, an insect repellent).

(c) EPA may approve an alternative child hazard warning that more appropriately reflects the nature of the pesticide product to which children may be exposed (for example, an impregnated pet collar). In this case, EPA may also approve placement on other than the front panel.

40 C.F.R. § 156.68. First Aid Statement.

(a) *Product as sold and distributed.* Each product must bear a first aid statement if the product has systemic effects in Category I, II, or III, or skin or eye irritation effects in Category I or II.

(b) *Product as diluted for use.* If the product labeling bears directions for dilution with water prior to use, the label may also include a statement describing how the first aid measures may be modified for the diluted product. Such a statement must reflect the Toxicity Category(ies) of the diluted product, based upon data for the route of exposure (or calculations if appropriate). If the labeling provides for a range of use dilutions, only that use dilution representing the highest concentration allowed by labeling may be used as the basis for a statement pertaining to the diluted product. The statement for a diluted product may not substitute for the statement for the concentrate, but augments the information provided for the concentrate.

(c) *Heading.* The heading of the statement may be "First Aid" or "Statement of Practical Treatment."

(d) *Location of first aid statement.* The first aid statement must appear on the front panel of the label of all products assigned to Toxicity Category I by any route of exposure. Upon review, the Agency may permit reasonable variations in the placement of the first aid statement if a reference such as "See first aid statement on back panel" appears on the front panel. The first aid statement for products assigned to Toxicity Categories II or III may appear on any panel of the label.

40 C.F.R. § 156.70. Precautionary statements for human hazards.

(a) *Requirement.* Human hazard and precautionary statements as required must appear together on the label or labeling under the general heading "Precautionary Statements" and under appropriate subheadings similar to "Humans and Domestic Animals," "Environmental Hazards" (see subpart E of this part) and "Physical or Chemical Hazards." The phrase "and Domestic Animals" may be omitted from the heading if domestic animals will not be exposed to the product.

(b) *Content of statements.* When data or other information show that an acute hazard may exist to humans or domestic animals, the label must bear precautionary statements describing the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or toxic effect or to mitigate the effect. The precautionary paragraph must be immediately preceded by the appropriate signal word.

(c) *Typical precautionary statements.* The table below presents typical hazard and precautionary statements. Specific statements pertaining to the hazards of the product and its uses must be approved by the Agency. With Agency approval, statements may be augmented to reflect the hazards and precautions associated with the product as diluted for use. Refer to § 156.68(b) for requirements for use dilution statements.

TYPICAL HUMAN HAZARD AND PRECAUTIONARY STATEMENTS

Toxicity Category	Systemic effects (oral, dermal, inhalation toxicity)	Irritation effects (skin and eye)	Sensitizer (There are no categories of sensitization.)
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel first aid statement required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Front panel first aid statement required.]	If product is a sensitizer: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
II	May be fatal if swallowed. [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statement required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]	
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]	Avoid contact with skin, eyes or clothing.	
IV	No precautionary statements required	No precautionary statements required.	

40 C.F.R. § 156.78. Precautionary statements for physical or chemical hazards.

(a) *Requirement.* Warning statements on the flammability or explosive characteristics of the pesticide product are required if a product meets the criteria in this section. Warning statements pertaining to other physical/chemical hazards (e.g., oxidizing potential, conductivity, chemical reactions leading to production of toxic substances) may be required on a case-by-case basis.

(b) *Pressurized products.* The table below sets out the required flammability label statements for pressurized products.

FLAMMABILITY STATEMENTS FOR PRESSURIZED PRODUCTS

–Flash point/flame extension of product	Required labeling statement
–Flash point at or below 20 deg. F OR –Flashback at any valve opening	*Extremely flammable.* Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130 deg. F may cause bursting.

–Flash point <ls-thn-eq> 20 deg. F to 80 deg. F	*Flammable.* Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 deg. F may cause bursting.
OR	
–Flame extension more than 18 in. long at a distance of 6 in from the flame	
All other pressurized products	*Contents under pressure.* Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 deg. F may cause bursting.

(c) *Non-pressurized products.* The table below sets out the required flammability label statements for non-pressurized products.

FLAMMABILITY STATEMENTS FOR NON-PRESSURIZED PRODUCTS

Flash point	Required labeling statement
At or below 20 deg. F	*Extremely flammable.* Keep away from fire, sparks and heated surfaces.
Greater than 20 deg. F to 80 deg. F	*Flammable.* Keep away from heat and open flame.
Greater than 80 deg. F to 150 deg. F	*Combustible.* Do not use or store near heat or open flame.

(d) *Total release fogger products.* (1) A *total release fogger* is defined as a pesticide product in a pressurized container designed to automatically release the total contents in one operation, for the purpose of creating a permeating fog within a confined space to deliver the pesticide throughout the space.

(2) If a pesticide product is a total release fogger containing a propellant with a flash point at or below 20 deg. F, then the following special instructions must be added to the "Physical and Chemical Hazards" warning statement, in addition to any flammability statement required by paragraph (b) of this section:

This product contains a highly flammable ingredient. It may cause a fire or explosion if not used

properly. Follow the Directions for Use on this label very carefully.

(3) A graphic symbol depicting fire, such as illustrated in this paragraph, or an equivalent symbol, must be displayed along with the required language adjoining the "Physical and Chemical Hazards" warning statement. The graphic symbol must be no smaller than twice the size of the first character of the human hazard signal word.

Highly Flammable Ingredient

Ingrediente Altamente Inflamable

40 C.F.R. § 158.540. Plant protection data requirements.

(a) *Table.* Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the plant protection data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns								Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Target area phytotoxicity	(1)	.....	.....	.....	.....	.....	.....	.....	.....	.....	EP	EP	121–1
Nontarget area phytotoxicity.											TGAI	TGAI	122–1
Tier I:													
Seed germination/seedling emergence.	(2)	.....	R	.....	R	.....	.....	R	.....	.....	TGAI	TGAI	122–1
Vegetative vigor	(2)	.....	R	.....	R	.....	.....	R	.....	.....	TGAI	TGAI	122–2
Aquatic plant growth	(2)	.....	R	.....	R	.....	.....	R	.....	.....	TGAI	TGAI	123–1
Tier II:													
Seed germination/seedling emergence.	(3)	.....	CR	.....	CR	.....	.....	CR	.....	.....	TGAI	TGAI	123–1
Vegetative vigor	(3)	.....	CR	.....	CR	.....	.....	CR	.....	.....	TGAI	TGAI	123–2
Aquatic plant growth	(4)	.....	CR	.....	CR	.....	.....	CR	.....	.....	TEP	TEP	124–1
Tier III:													
Terrestrial field	(3)	.....	CR	.....	CR	.....	.....	CR	.....	.....	TEP	TEP	124–2
Aquatic field	(4)	.....	CR	.....	CR	.....	.....	CR	.....	.....			

Key: CR=Conditionally required; TGAI=Technical grade of the active ingredient; EP=End-use product; TEP=Typical end-use product.

(b) NOTES. The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Data are required for Special Review and certain public health situations.

(2) Data are required for pesticides to be used in forests and natural grasslands. For herbicide used in forest site preparation; the aquatic plant growth tests will be required. Data are required to support products to be used in other locations when any of the following conditions are met:

(i) Phytotoxicity problems concerning the product arise and open literature data are not available to address the problems.

(ii) The product may pose hazards to endangered or threatened species.

(iii) Special Review has been initiated on the product.

(3) Required if a 25 percent or greater detrimental effect was found in 1 or more plant species in the corresponding test of the previous tier.

(4) Required if a 50 percent or greater detrimental effect was found on any plant species in the corresponding test of the previous tier.

40 C.F.R. § 158.640. Product performance data requirements.

(a) *Table.* Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the product performance data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Efficacy of antimicrobial agents													
Products for use on hard surfaces.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–2
Products requiring confirmatory data.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–3
Products for use on fabrics and textiles.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–4
Air sanitizers	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–5
Products for control of microbial pests associated with human and animal wastes.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–7
Products for treating water systems.	(1)	.....	.....	[CR]	.....	.....	.....	.....	.....	CR	.....	EP*	91–8
Efficacy of fungicides and nematicides													
Products for control of organisms producing mycotoxins.	(1)	[CR]	.....	[CR]	.....	[CR]	.....	.....	.....	.....	.....	EP*	93–16
Efficacy of Vertebrate Control Agents													
Avian toxicants	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	(R)	.....	EP*	96–5
Avian repellents	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	.....	.....	EP*	96–6
Avian frightening agents ..	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	.....	.....	EP*	96–7
Bat toxicants and repellents.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	(R)	.....	EP*	96–9
Commensal rodenticides ..	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	(R)	TEP	EP*	96–10
Rodenticides on farm and rangelands.	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	.....	.....	EP*	96–12
Rodent fumigants	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	(R)	.....	EP*	96–13
Rodent reproductive inhibitors.	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	(R)	.....	EP*	96–16
Mammalian predacides	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	.....	.....	EP*	96–17

Key: R=Required; CR=Conditionally required; [ ]=Brackets (i.e., [R], [CR]) indicate data requirements that apply to products for which an experimental use permit is being sought; EP=End-use product* (asterisk identifies those data requirements that end-use applicants (i.e., "formulators") must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source); MP=Manufacturing use product; TEP=Typical end-use product.

(b) Notes: The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) The Agency has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

(2) [Reserved]

40 C.F.R. § 159.184. Toxic or adverse effect incident reports.

(a) *General.* Information about incidents affecting humans or other non-target organisms must be submitted if the following three conditions are met:

(1) The registrant is aware, or has been informed that a person or non-target organism may have been exposed to a pesticide.

(2) The registrant is aware, or has been informed that the person or non-target organism suffered a toxic or adverse effect, or may suffer a delayed or chronic adverse effect in the future.

(3) The registrant has or could obtain information concerning where the incident occurred, the pesticide or product involved, and the name of a person to contact regarding the incident.

(b) *Exceptions.* Information regarding an incident need not be submitted if any of the following conditions are met:

(1) The registrant is aware of facts which clearly establish that the reported toxic effect, or reported exposure, did not or will not occur.

(2) The registrant has been notified in writing by the Agency that for this incident or category of incidents, and the registrant has not been notified in writing by the Agency that the waiver is rescinded.

(3) It concerns a toxic effect to non-target plants, which were at the use site at the time the pesticide was applied, if the label provides adequate notice of such a risk.

(4) It concerns non-lethal phytotoxicity to the treated crop if the label provides an adequate notice of such a risk.

(5) It concerns a toxic effect to pests not specified on the label, provided that such pests are similar to pests specified on the label.

(6) It concerns minor skin or eye irritation effects warned of on the label of a product which is registered for use in residential use sites, and the effects occurred as a result of use in a residential site.

(c) *Required information on individual incidents.* To the extent that the registrant has any of the information listed in paragraphs (c)(1) through (c)(4) of this section, the registrant must supply the information on each pesticide incident that meets the requirements outlined in paragraph (a) of this section. If the registrant acquires additional information concerning an incident previously reported to the Agency under this part, such information shall be reported if it meets the criteria set forth in paragraph (f) of this section. In the future, the Agency may by notice specify a format for such submissions. The Administrative, Pesticide, Circumstance and Exposure Type(s) of information must be reported for individual incidents, except where the provisions of paragraph (e) of this section allow for aggregated summary forms of reporting, or if EPA in the future grants permission in writing for alternative reporting formats. The registrant must also provide one or more Exposure Type and Severity categories and their designations for each incident as set forth in paragraph (c)(5) of this section, depending on the applicability of the criteria listed below. The criteria listed should be used in assigning a category. For example, an incident which allegedly caused serious but non-fatal effects to human beings and domestic animals might be designated "H-B: D-B." When a single incident involves multiple pesticides, the registrant need only report on their specific product. However, if a single incident involves more than one type of non-target organism–for example, both humans and domestic animals are involved–all appropriate available information dealing with each of the victims must also be reported. The informational items

below are grouped by sections for ease in reporting pesticide incidents.

(1) *Administrative.* Pesticide incident reports must be submitted if the registrant possesses or receives any of the following information, and the incident meets the minimum requirements set forth in paragraph (a) of this section:

(i) Name of reporter, address, and telephone number.

(ii) Name, address, and telephone number of contact person (if different than reporter).

(iii) Incident report status (e.g., new or update); if update, include the date of original submission.

(iv) Date registrant became aware of the incident.

(v) Date of incident (if appropriate, list start and end dates).

(vi) Location of incident (city, county and state).

(vii) Is incident part of a larger study.

(viii) Source if different from reporting registrant.

(2) *Pesticide.* Pesticide incident reports must be submitted for each pesticide that may have contributed to the incident, if the registrant possesses or receives any of the following information, and the incident meets the minimum requirements set forth in paragraph (a) of this section:

(i) Product name.

(ii) Active ingredient(s).

(iii) EPA Registration Number.

(iv) Diluted for use, or concentrate.

(v) Formulation, if known.

(3) *Circumstance.* Pesticide incident reports must be submitted if the registrant possesses or receives any of the following information, and the incident meets the

minimum requirements set forth in paragraph (a) of this section:

(i) Evidence the label directions were not followed (e.g., yes, no, unknown).

(ii) How exposed (e.g., spill, drift, equipment failure, container failure, mislabeling, runoff, etc.).

(iii) Situation (e.g., household use, mixing/loading, application, reentry, disposal, transportation, other (describe)).

(iv) Use site (e.g., home, yard, commercial turf, agricultural (specify crop), industrial, building/office, school, nursery, greenhouse, pond/lake/stream, well, forest/woods, other.

(v) Applicator certified (yes, no, unknown).

(vi) A brief description of the circumstances of the incident.

(4) *Other incident specific information.* Pesticide incident reports must be submitted if the registrant possesses or receives any of the following information, and the incident meets the minimum requirements set forth in paragraph (a) of this section:

(i) If the incident involves humans:

(A) Route of exposure (skin, eye, respiratory, oral).

(B) List signs/symptoms/adverse effects.

(C) If laboratory tests were performed, list name of test(s) and results.

(D) If available, submit laboratory report(s).

(E) Time between exposure and onset of symptoms.

(F) Was adverse effect the result of suicide/homicide or attempted suicide/homicide.

(G) Type of medical care sought, (e.g., none, Poison Control Center, hospital emergency department, hospital inpatient, private physician, clinic, other).

(H) Demographics (sex, age, occupation).

(I) If female, pregnant?

(J) Exposure data: amount of pesticide; duration of exposure; weight of victim.

(K) Was exposure occupational; days lost due to illness.

(L) Was protective clothing worn (specify).

(ii) If domestic animal:

(A) Type of animal (e.g., livestock, poultry, bird, fish, household pet e.g., dog/cat etc.).

(B) List signs/symptoms/adverse effects.

(C) Breed/species (name and number affected, per adverse effect).

(D) Route of exposure (e.g., skin, eye, respiratory, oral).

(E) Time between exposure and onset of symptoms.

(F) If laboratory test(s) performed, list name of tests and results.

(G) If available, submit laboratory report(s).

(iii) If fish, wildlife, plants or other non-target organisms:

(A) List species affected, and number of individuals per species.

(B) List symptoms or adverse effects.

(C) Magnitude of the effect (e.g., miles of streams, square area of terrestrial habitat).

(D) Pesticide application rate, intended use site (e.g., corn, turf), and method of application.

(E) Description of the habitat and the circumstances under which the incident occurred.

(F) If plant, type of plant life (i.e., crop, forest, orchard, home garden, ornamental, forage).

(G) Formulation of pesticide if not indicated by brand name (granular, flowable).

(H) Distance from treatment site.

(I) If laboratory test(s) performed, list name of test(s) and results.

(J) If available, submit laboratory report(s).

(iv) If surface water:

(A) If raw water samples, water bodies sampled and approximate locations in each water body.

(B) If raw water samples, proximity of sampling locations to drinking water supply intakes and identities of systems supplied.

(C) If finished water samples, water supply systems sampled.

(D) If finished water samples, percent surface water source by specific surface water sources to water supply system(s).

(E) Sample type (grab, composite).

(F) Sampling times/frequency.

(G) Pesticides and degredates analyzed for, the detection limits, and the amount detected.

(H) Method of analysis.

(v) If ground water:

(A) Pesticides and degredates analyzed for, the analytical method used, the detection limits, and the amount detected.

(B) Sample date.

(C) Amount pesticide applied (lbs-ai/acre).

(D) Date of last application.

(E) Depth to water.

(F) Latitude/longitude.

(G) Soil series and texture (sand/silt/clay).

(H) Frequency of applications per year.

(I) Aquifer description (confined/unconfined).

(J) Method of application.

(K) Years pesticide used.

(L) Well use and well identifier.

(M) Screened interval.

(N) Annual cumulative rainfall (inches).

(O) Maximum rainfall and date.

(P) Cumulative irrigation (inches).

(Q) Hydrologic group.

(R) Hydraulic conductivity.

(S) pH.

(T) Organic matter or organic carbon (percent).

(vi) If property damage.

(A) Provide description.

(B) [Reserved]

(5) *Exposure types and severity category designations–* (i) *Humans.* If an effect involves a human, provide the appropriate 2-letter exposure types and severity categories and their designations, based upon the following categories:

(A) H-A: If the person died.

(B) H-B: If the person alleged or exhibited symptoms which may have been life-threatening, or resulted in adverse reproductive effects or in residual disability.

(C) H-C: If the person alleged or exhibited symptoms more pronounced, more prolonged or of a more systemic nature than minor symptoms. Usually some form of treatment of the person would have been Indicated. Symptoms were not life threatening and the person has returned to his/her pre-exposure state of health with no additional residual disability.

(D) H-D: If the person alleged or exhibited some symptoms, but they were minimally traumatic. The symptoms

resolved rapidly and usually involve skin, eye or respiratory irritation.

(E) H-E: If symptoms are unknown, unspecified or are alleged to be of a delayed or chronic nature that may appear in the future.

(ii) *Domestic animals.* If an effect involves a domestic animal, provide the appropriate 2-letter notation based upon the following categories:

(A) D-A: If the domestic animal died or was euthanized.

(B) D-B: If the domestic animal exhibited or was alleged to have exhibited symptoms which may have been life-threatening or resulted in residual disability.

(C) D-C: If the domestic animal exhibited or was alleged to have exhibited symptoms which are more pronounced, more prolonged or of a more systemic nature than minor symptoms. Usually some form of treatment would have been indicated to treat the animal. Symptoms were not life threatening and the animal has returned to its pre-exposure state of health with no additional residual disability.

(D) D-D: If the domestic animal was alleged to have exhibited symptoms, but they were minimally bothersome. The symptoms resolved rapidly and usually involve skin, eye or respirator irritation.

(E) D-E: If symptoms are unknown or not specified.

(iii) *Fish or wildlife.* If an alleged effect involves fish or wildlife, label the incident W-A if any of the following criteria are met, or W-B if none of the criteria are met:

(A) Involves any incident caused by a pesticide currently in Formal Review for ecological concerns.

(B) Fish: Affected 1,000 or more individuals of a schooling species or 50 or more individuals of a non-schooling species.

(C) Birds: Affected 200 or more individuals of a flocking species, or 50 or more individuals of a songbird species, or 5 or more individuals of a predatory species.

(D) Mammals, reptiles, amphibians: Affected 50 or more individuals of a relatively common or herding species or 5 or more individuals of a rare or solitary species.

(E) Involves effects to, or illegal pesticide treatment (misuse) of a substantial tract of habitat (greater than or equal to 10 acres, terrestrial or aquatic).

(F) Involves a major spill or discharge (greater than or equal to 5,000 gallons) of a pesticide.

(G) Involves adverse effects caused by a pesticide, to federally listed endangered or threatened species.

(iv) *Plants.* If an alleged effect involves damage to plants, label the incident P-A if the following criterion is met, or P-B if the criterion is not met:

(A) The effect is alleged to have occurred on more than 45 percent of the acreage exposed to the pesticide.

(B) [Reserved]

(v) *Other non-target organisms.* If an alleged effect involves damage to non-target organisms other than fish, wildlife or plants (for example, beneficial insects), label the incident ONT.

(vi) *Water contamination.* If a pesticide is alleged to have been detected in groundwater, surface water or finished drinking water, label the incident in accordance with the following criteria:

(A) G-A: If the pesticide was detected at levels greater than the maximum contaminant level (MCL) or health advisory level (HAL) or an applicable criterion for ambient water quality.

(B) G-B: If the pesticide was detected at levels greater than 10 percent of the MCL, HAL or a criterion for ambient water quality but does not exceed the MCL or other applicable level.

(C) G-C: If the pesticide was detected at levels less than 10 percent of the MCL, HAL, or other applicable level, or there is no established level of concern.

(vii) *Property damage.* If an incident involves alleged property damage the applicable term(s) shall be included along with any other applicable effect category label; for example, "H-B: property damage." Label the incident in accordance with the following criteria:

(A) PD-A: The product is alleged to have caused damage in a manner that could have caused direct human injury, such as fire or explosion.

(B) PD-B: The product is alleged to have caused damage in excess of $5,000.

(C) PD-C: Any allegation of property damage that does not meet the criteria of paragraphs (c)(5)(vii)(A) or (B) of this section, including cases in which the level of damages is not specified.

(d) *Time requirements for submitting incident information.* Information concerning incidents reportable under this section must be submitted within the time frames listed for different exposure and severity categories, as follows:

(1) For allegations involving human fatality (H-A), registrants must submit the required information, to the extent it is available, no later than 15 days after learning of an allegation.

(2) Information concerning incidents which meet the criteria for the following exposure and severity category labels described in paragraph (c)(5) of this section, reports of detections of pesticides in water, and efficacy failure incidents may be described in § 159.188(a)(1) and (b)(1), may be accumulated for a 30-day period, and submitted to the Agency within 30 days after the end of each 30-day accumulation period for: Humans, H-B, and H-C; Wildlife, W-A; Plants, P-A; Water, G-A; Property Damage, PD-A.

(3) Incidents or reports of detections of pesticides in water meeting all other exposure and severity label categories, information may be accumulated by registrants for 90 days and submitted within 60 days after the end of each 90-day accumulation period.

(e) *Aggregated reports.* For incidents that are reportable under the schedule requirements of paragraph (d)(3) of this section, in lieu of individual reports containing the information listed in paragraphs (c)(1) through (c)(4) of this section, registrants must provide an aggregated report listing:

(1) The time period covered by the report.

(2) For each exposure and severity label category, a count of the number of incidents, listed by product registration number (if known) or active ingredient.

(3) A count of domestic animal incidents in categories, other than D-A or D-B, which can be added together and reported as a single number.

(f) *Reporting additional information.* If, after the submission of an incident report to the Agency, a registrant acquires additional information concerning that incident, the information should be submitted within the same time frame as applied to the original incident report, if any of the following conditions apply:

(1) The information concerns an alleged human fatality (H-A), and the information consists of any of the elements listed in paragraphs (c)(1) through (c)(4) of this section.

(2) The information concerns an incident originally reported as alleging a major human illness or injury (H-B), or fatality to a domestic animal (D-A), or wildlife (W-A), and the additional information consists of pesticide or circumstance information listed in paragraphs (c)(2) or (c)(3) of this section, or is a laboratory report concerning persons or animals involved in the incident.

(3) The information concerns any incident not originally reported with one of the exposure and severity labels H-A,

or H-B for human incidents, or at the "A" level of severity for any other exposure or incident type, and the new information would result in labeling the incident H-A or H-B for a human incident, or at the "A" level of severity for any other exposure or incident type listed in paragraph (c)(5) of this section.

40 C.F.R. § 162.153. State registration procedures.

* * * * *

(e) *Labeling requirements.* (1) Prior to issuing any registration, the State shall review the proposed labeling submitted with the application to determine compliance with this paragraph. In addition, the State shall review a copy of the final printed labeling as soon as practical after a registration is issued in order to verify compliance with this paragraph.

(2) For a new product, the State must, as a condition of the registration, require that the product be accompanied from the time it enters the stream of commerce by labeling meeting all applicable criteria of § 156.10 of this chapter. New product labeling must all contain:

(i) A statement identifying the State where registration is to be valid.

(ii) The special local need registration number assigned by the State.

(3) Except as provided in paragraph (e)(4) of this section, as a condition for a registration of an additional use of a federally registered product, the State must require that at the time of sale to users, labeling from the federally registered product be accompanied by supplemental labeling which contains:

(i) A statement identifying the State where registration is valid.

(ii) Directions for use to meet the special local need which satisfy the criteria of § 156.10(i) of this chapter.

(iii) The trade name of the product.

(iv) The name and address of the section 24(c) registrant.

(v) The EPA registration number of the federally registered product.

(vi) The special local need registration number assigned by the State.

(vii) A statement prohibiting use of the product in a manner inconsistent with all applicable directions, restrictions, and precautions found in the labeling of the federally registered product and accompanying supplemental labeling.

(4) When a federally registered product is already in the stream of commerce at the time the State issues a registration for an additional use of that product, the State must ensure that supplemental labeling for the additional use, meeting the criteria of paragraph (e)(3) of this section, is made available to purchasers and users of the product within 45 days of the date on which the State approves the final printed supplemental labeling.

(5) If a State classifies for restricted use a product or use registered by the State, which is not required to be so classified by paragraph (g) of this section, then the State may require supplemental labeling for the product or use containing additional appropriate precautions, and a statement that the product or use is for restricted use within that State.

* * * * *

Supreme Court, U.S.
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No. 03-388

IN THE

Supreme Court of the United States

DENNIS BATES, *et al.*,

Petitioners,

v.

DOW AGROSCIENCES LLC,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR RESPONDENT

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QUESTION PRESENTED

Whether petitioners' claims for crop damages—which turn on the contention that respondent had a state-law obligation to warn them that its pesticide was not suitable for use on soils with elevated pH levels—are expressly or impliedly preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136-136y.

CORPORATE DISCLOSURE STATEMENT

Respondent Dow AgroSciences LLC is a wholly owned subsidiary of The Dow Chemical Company.

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STATEMENT

A. Statutory and Regulatory Background

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or Act), 7 U.S.C. §§ 136-136y, is a "comprehensive regulatory statute" governing the manufacture, use, sale, and labeling of pesticides. *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. 986, 991 (1984). The Act represents Congress's considered response to decades of experience in federal oversight of the marketing and labeling of agricultural products.

1. The first significant federal foray into the regulation of agricultural chemicals was the Insecticide Act of 1910, ch. 191, 36 Stat. 331. The Insecticide Act prohibited the interstate transportation and sale of "misbranded" insecticides. *Id.* § 2, 36 Stat. 331. That Act was enforced principally through criminal prosecutions. *Id.* §§ 3-4, 36 Stat. 331-332. A substance was "misbranded" if the package or label contained any statement about the substance that was "false or misleading in any particular." *Id.* § 8, 36 Stat. 333.

FIFRA, as enacted in 1947, expanded federal authority over agricultural chemicals, but the law was nonetheless "primarily a licensing and labeling statute." *Ruckelshaus*, 467 U.S. at 991. The original version of FIFRA contained two important measures absent from its predecessor. First, the Act required registration of all pesticides with the Secretary of Agriculture and made sale of any unregistered product unlawful. FIFRA, ch. 125, §§ 3-4, 61 Stat. 166-167 (1947). Second, the Act imposed specific requirements for pesticide labels, *see id.* § 3(a)(2)-(3), 61 Stat. 166, and again prohibited the manufacture or sale of any "misbranded" substance, *id.* § 3(a)(5), 61 Stat. 166. FIFRA's requirements for pesticide labels reflected Congress's concern that "that the laws governing [pesticides] be as nearly uniform as possible consistent with the need for the protection of the public, so that manufacturers may have Nation-wide distribution with a minimum of conflict between the labeling requirements of the various laws." H.R. Rep. No. 80-313, at 3 (1947).

Despite these advancements and subsequent attempts to strengthen the Act, by the late 1960s there emerged "a growing perception that the existing legislation was not equal to the task of safeguarding the public interest." *Ruckelshaus*, 467 U.S. at 991. Congress also perceived "serious deficiencies" in FIFRA's enforcement and administration by the Department of Agriculture.[1] In the absence of an effective federal regime governing pesticides, various States moved to exercise regulatory authority over agricultural chemicals. By the end of the 1960s, 47 states had enacted pesticide laws, many of which prescribed disparate duties and standards on an industry that had long since operated on a national scale.[2] Compounding the shortcomings in FIFRA, therefore, was a confusing patchwork of regulation and enforcement with no clear division between the domains of federal and state law.

These problems proved particularly disruptive of effective regulation in the area of "FIFRA's historic focus," pesticide labeling. *See Wisconsin Pub. Intervenor* v. *Mortier*, 501 U.S. 597, 613 (1991). Lax enforcement of the 1947 Act's labeling provisions produced "warning statements and directions for use . . . [that] were confusing or even directly contradictory." H.R. Rep. No. 91-637, at 15 (1969). The result was that "most pesticide users [did] not read labels and those who [did had] difficulty understanding them." *Id.*

2. Against this backdrop, Congress comprehensively revised FIFRA in 1972. *See* S. Rep. No. 92-838, pt. I, at 1; (1972); *Ruckelshaus*, 467 U.S. at 991. Having transferred authority over the Act to the newly formed Environmental Protection Agency (EPA), Congress sought to remedy

[1] *See* H.R. Rep. No. 91-637, at 1-2 (1969); William H. Rodgers, Jr., *The Persistent Problem of the Persistent Pesticides: A Lesson in Environmental Law*, 70 Colum. L. Rev. 567, 570-574 (1970).

[2] *See Federal Pesticide Control Act of 1971: Hearings Before the House Comm. on Agriculture*, 92d Cong., 1st Sess. 21-23 (1971); Note, *Agricultural Pesticides: The Need for Improved Control Legislation*, 52 Minn. L. Rev. 1242, 1254 (1968).

FIFRA's structural flaws in a number of respects: granting EPA increased enforcement authority; providing for review, cancellation, and suspension of registrations; and "significantly strengthen[ing] [the Act's] registration and labeling standards." *Mortier*, 501 U.S. at 601.

To clarify the regulatory spheres occupied by the federal government and the States, and to make regulation by each more robust, Congress also enacted 7 U.S.C. § 136v.[3] That section provides in relevant part:

> **(a) In general**
>
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.
>
> **(b) Uniformity**
>
> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

Accordingly, after the 1972 amendments, States retain authority to regulate pesticide *use* (subject to prohibitions imposed by FIFRA), but federal law exclusively governs all aspects of pesticide *labeling* and *packaging*. *See* H.R. Rep. No. 92-511, at 1-2 (1972) ("State authority to change Federal labeling and packaging is completely preempted."); *id.* at 16 ("[T]he Committee has adopted language which is intended to completely preempt State authority in regard to labeling

[3] As initially enacted in 1972, the two subsections of § 136v had slightly different language and did not contain separate headings. Congress reenacted those provisions, with slight language changes, in 1978, at the same time that it expressly granted to EPA the authority to waive its review of efficacy data when determining whether a pesticide should be registered (*see* pp. 5-6, *infra*). *See* Pub. L. No. 95-396, § 22, 92 Stat. 819, 835 (1978). Section 136v(b) was again amended in 1988 to insert the heading "Uniformity" immediately preceding the text of the express preemption clause. Pub. L. No. 100-532, § 801(m)(2), 102 Stat. 2654, 2682 (1988).

and packaging."); S. Rep. No. 92-838, pt. I, at 30 ("Subsection (b) preempts any State labeling or packaging requirements differing from such requirements under the Act").

When Congress amended FIFRA in 1972, it also considered the possibility of enforcement of the Act's requirements and prohibitions through private rights of action. A proposed provision for private civil actions to enforce FIFRA also would have preserved the right of individuals to pursue common-law claims. *See* S. Rep. No. 92-970, at 4-5 (1972); S. Rep. No. 92-838, pt. II, at 39-41. The Senate Agriculture Committee rejected private enforcement, stressing that such suits could "interfere with the orderly administration of the law." *Id.* at 39. Although a provision for private enforcement, with a savings clause, passed the Senate, it was rejected by the Conference Committee. H.R. Conf. Rep. No. 92-1540, at 34 (1972).

3. The cornerstone of pesticide regulation under FIFRA, as amended in 1972, was the requirement that all pesticides must be registered by EPA. 7 U.S.C. § 136a(a), (c)(5); *see* § 136j(a)(1)(A) ("[I]t shall be unlawful for any person . . . to distribute or sell . . . any pesticide that is not registered under Section 136a"). To grant registration, EPA was required to make four determinations, *id.* § 136a(c)(5)(A)-(D), including that the pesticide's "composition is such as to warrant the proposed claims for it," *id.* § 136a(c)(5)(A)—*i.e.*, that the pesticide worked as claimed in the label. Although Congress did not expressly require registrants to submit any particular kinds of data to EPA in support of their applications, it granted EPA broad discretion to demand data in support of registration applications, *see* Pub. L. No. 92-516, § 3(c), 86 Stat. 973, 979-980 (1972), and EPA has exercised that authority by requiring applicants to submit a battery of studies on virtually every aspect of the pesticide, *see* 40 C.F.R. pt. 158.

The 1972 amendments quickly resulted in a massive logjam in the registration of pesticides. *See* S. Rep. No. 95-334, at 3 (1977). On revisiting the issue, Congress determined that the registration process was in need of adjustment.

Thus, in 1978, Congress clarified that EPA need not require compliance with onerous data submission obligations before permitting a pesticide to be sold in commerce, and instead could register products "conditionally," *i.e.*, without having all the data necessary to support unconditional registration. A conditionally registered product may be introduced into commerce, but conditional registration does not obviate the legal requirement that the pesticide comply with federal law, including the labeling requirements imposed under FIFRA. *See* 7 U.S.C. § 136a(c)(7); S. Rep. No. 95-334, at 20-21; H.R. Rep. No. 95-663, at 28 (1977); 48 Fed. Reg. 34,000, 34,001 (1983).

EPA also advised Congress that, based on the agency's experience in implementing the Act, it was often inefficient and unnecessary for EPA to evaluate data regarding a pesticide's "efficacy"—how well it controls pests, and whether it damages the target crop—as a condition of registration. According to the EPA Administrator, "the registrant, the USDA, and pesticide users are generally in a better position to judge efficacy, particularly of agricultural pesticides." H.R. Rep. No. 95-343, pt. I, at 9 (1977). EPA therefore requested "explicit authority to waive the efficacy data requirement when appropriate." *Id.* EPA emphasized, however, that it did "not believe that the efficacy requirement should be removed from the Act entirely," and thus further advised that the agency "should also have the authority to cancel products which have proven to be inefficacious." *Id.*

Congress agreed that EPA should focus its administrative resources in the registration process on matters other than efficacy review:

> The expenditure of resources by the Environmental Protection Agency in reviewing efficacy data is not the best use of resources since a pesticide manufacturer is not likely to expend the substantial investment in time and money needed to obtain registration of a pesticide on a non-efficacious product. The Department of Agriculture and the State agricultural experiment stations are constantly checking

> pesticide efficacy. Further, the farmer and professional pesticide applicators are competent judges of pesticide efficacy.

S. Rep. No. 95-334, at 9; *see id.* at 38, 65.

Accordingly, as EPA had requested, Congress provided the agency "explicit authority" to waive review of the efficacy of a pesticide in the initial registration process. 7 U.S.C. § 136a(c)(5) (flush paragraph). EPA, in turn, promulgated regulations that allow manufacturers to apply for pesticide registration or conditional registration without submitting efficacy data. *See* 40 C.F.R. § 158.640(b)(1). Manufacturers must, however, continue to "ensure through testing that [their] products are efficacious when used in accordance with label directions and commonly accepted pest control practices," and EPA "reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration." *Id.*

4. Registration of any pesticide is conditioned on a determination by EPA that, *inter alia*, the pesticide's "labeling . . . compl[ies] with the requirements of [FIFRA]," 7 U.S.C. § 136a(c)(5)(B).[4] FIFRA also prohibits the distribution or sale of any pesticide that is "misbranded." *Id.* § 136j(a)(1)(E). The Act defines that term in detail to include labeling not only that is "false or misleading in any particular," *id.* § 136(q)(1)(A), but also that fails to contain "any word, statement, or other information required by or under the authority of this subchapter to appear on the label or labeling." *Id.* § 136(q)(1)(E). Under the Act, such information must be "prominently placed [on the label] with such conspicuousness . . . and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of use." *Id.* § 136(q)(1)(E) and (H), (q)(2)(A) and (C). The Act also sets forth a number of specific categories of information without which the product will be deemed misbranded. *Id.* § 136(q)(1)-(2).

[4] "The term 'label' means the written, printed or graphic matter on, or attached to, the pesticide . . . or any of its containers or wrappers." 7 U.S.C. § 136(p)(1). "The term 'labeling' means all labels and all other written, printed or graphic matter accompanying the pesticide . . . at any time; or to which reference is made on the label or in literature accompanying the pesticide." *Id.* § 136(p)(2).

EPA regulations supplement these statutory instructions with specific directives about the content, placement, type size, and prominence of all information that appears on the label. *See generally* 40 C.F.R. pt. 156; *Papas* v. *Upjohn Co.*, 926 F.2d 1019, 1024 (11th Cir 1991) ("EPA has regulated almost every aspect of pesticide labeling"). Those regulations specify the precise positioning, font size, wording and color of hazard warnings and precautionary statements about the product's effects on human health, the environment, and agricultural workers. 40 C.F.R. §§ 156.10(a), 156.60, 156.62, 156.64, 156.70-156.78, 156.80, 156.86, 156.200-156.212. They also dictate the substance of the label's "directions of use," which "must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment," *id.* § 156.10(i)(1)(i). In addition, the regulations give precise content to the terms "false and misleading" in FIFRA's misbranding provision, establishing EPA's construction of those terms and furnishing examples indicating the manner in which the agency applies them. *Id.* § 156.10(a)(5).

EPA possesses sole authority to approve all proposed labeling and may order any changes necessary to ensure that the label complies with FIFRA. 40 C.F.R. §§ 152.112(f), 156.10(a)(6). Following such label approval and successful registration (or, as is more common today, conditional registration), "[a] registrant may distribute or sell [the] registered product with the composition, packaging and labeling currently approved by the Agency." *Id.* § 152.130(a). Thereafter, the label may not be changed, except in the most minor and technical ways, without EPA permission. *See* 7 U.S.C. § 136a(f)(1); 40 C.F.R. §§ 152.44, 152.46. The directions on an approved label carry the force of federal law, *see* 7 U.S.C. § 136j(a)(2)(G), and the labeling may not be "de-

tach[ed], alter[ed], deface[d], or destroy[ed], in whole or in part" on pain of criminal prosecution, *id.* § 136j(a)(2)(A).

5. Although EPA does not routinely scrutinize product efficacy in the initial registration process, efficacy remains an important focus of FIFRA's regulatory scheme. In addition to imposing a duty to test any pesticide to ensure its efficacy and to furnish testing data on request, federal law requires registrants to inform EPA if they learn that their products have harmed non-target organisms, including crops. *See* 40 C.F.R. § 159.184(a)(1). Moreover, a pesticide will be deemed misbranded if the label contains any "false or misleading statement concerning the effectiveness of the product as a pesticide or device." *Id.* § 156.10(a)(5)(i).

EPA has plenary power to remedy any FIFRA violation arising from a pesticide that proves to be inefficacious or misbranded. Where a violation is suspected, the agency may search manufacturing facilities, "seiz[e] any pesticide or device" that does not comply with the Act, 7 U.S.C. §§ 136g(b), 136k(b), and order recall, removal, and an immediate halt to all sale and use of the offending product, *id.* § 136k(a). EPA may refer the matter to the Attorney General for criminal prosecution, *id.* § 136g(c)(1), or impose civil penalties of not more than $5000 for each violation depending on "the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation," *id.* § 136*l*(a)(1), (4). EPA may also initiate proceedings to suspend or cancel the pesticide's registration, *id.* § 136d(b), with or without notice to the registrant, *id.* § 136d(b)(3). At the conclusion of those proceedings, EPA is instructed to take whatever action it deems appropriate in light of the "the impact . . . on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy." *Id.* §§ 136d(b); *see id.* § 136w(a)(2)(B). Successful initial registration is no defense to any such remedial action. *Id.* § 136a(f)(1).

In short, EPA continues to regulate the accuracy of label statements on product efficacy. The discretionary waiver of reviewing efficacy data in the initial registration process changes only the *manner* in which EPA regulates efficacy. "Products which are not effective do not meet the standard set by FIFRA section 3(c)(5)(A). Applications to register such products will be denied; existing registrations of products shown to be ineffective may be cancelled or the products may be deemed misbranded under FIFRA section 2(q)(1)(A)." 47 Fed. Reg. 57,624, 57,630 (1982); *see also* 64 Fed. Reg. 50,674-50,675 (1999).

B. Facts and Procedural History

1. In 1993, respondent Dow AgroSciences (DAS) began the process for federal registration of its new diclosulam-based herbicide, later named Strongarm®.[5] At that time, EPA had recently instituted a policy of expediting registration of pesticides with demonstrable environmental benefits; under that policy, EPA encouraged manufacturers to submit more extensive data, including data on efficacy (which, in light of EPA's waiver, was not usually required in the registration process).[6] *See* JA 237; 57 Fed. Reg. 32,140 (1992); 58 Fed. Reg. 5854 (1993).

Pursuant to that policy, DAS submitted a comprehensive body of data on Strongarm's efficacy in controlling broadleaf weeds in peanuts and its safety for that use.[7] For example, DAS submitted a 100-page review of studies of products containing diclosulam, the main active ingredient in Strongarm. J.E. Nelson & M.A. Rekeweg, *Public Interest Document for Products Containing Diclosulam* (1996). An entire chapter of that review was dedicated to a discussion

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[5] FIFRA's definition of "pesticide" includes substances intended to kill weeds. 7 U.S.C. § 136(t), (u). Accordingly, diclosulam is a pesticide covered by FIFRA.

[6] This policy was ultimately endorsed by Congress in 1996, *see* 7 U.S.C. § 136a(c)(10), and formalized in 1997 as the "Reduced-Risk Initiative," *see* JA 236-275.

[7] DAS's submissions are contained in the official EPA record of the registration application. For the convenience of the Court, we have offered to lodge these materials with the Clerk.

of the "Efficacy and Reduced Cost Benefits In Peanuts." *Id.* at 40-55. DAS pointed out that the underlying studies showed that "[s]oil moisture, texture, organic matter and pH as well as plant growth rate and herbicide dissipation affect the availability and uptake of diclosulam." *Id.* at 12. DAS also reported that "[i]n 1995 [its] field scientists initiated 14 efficacy field experiments and 20 injury field experiments to evaluate the weed control efficacy and crop response of diclosulam and the broadleaf herbicides it will replace in peanuts." *Id.* at 46. The resulting data consistently reflected no or negligible peanut crop injury. *Id.* at 48-54.[8]

In 1998, DAS submitted to EPA a 175-page study about diclosulam, *see* John J. Jachetta et al., *Reduced Risk Rationale for Diclosulam Herbicide Used in the Control of Broadleaf Weeds in Peanuts* (1998), which included a summary of efficacy studies (at 24-25). Appendix F of that study set forth eight research reports, each of which evaluated diclosulam's risk to peanuts, its efficacy on weeds infesting peanuts, and resulting peanut crop yields (which reflects both target-crop phytotoxicity and efficacy). Those reports demonstrated excellent safety in peanuts. *See id.* at 74-175.

EPA conditionally registered Strongarm on March 8, 2000. JA 63. In its notice of conditional registration, EPA advised DAS that "[c]hanges in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce." JA 63. EPA required DAS to submit four additional categories of product data and required that the Strongarm label be amended to include additional warnings and use instructions not later than February 28, 2001. JA 64-66. Failure to satisfy those conditions would have subjected Strongarm's registration to cancellation. JA 66.

[8] Petitioners assert that a 1992 study on the phytotoxicity of flumetsulam (a molecule different than diclosulam) on sunflower crops rotated into fields where soybeans had been treated with flumetsulam the prior year gave DAS reason to suspect that diclosulam would be phytotoxic to peanuts in high pH soils. *See* Pet. Br. 8. In fact, that study showed the direct opposite: "In high pH (> 7.0) soils flumetsulam *degraded* most rapidly" and "[i]njury to sunflowers (Table 4) was *least* in the site with a soil of *high* pH . . . and *greatest* in that with a soil of *low* pH[.]" R. 603 (emphasis added); *see also id.* at 604 ("[T]he lower level of sunflower injury at location 4 could have been due to faster degradation at higher soil pH . . . ."). That study is consistent with EPA's determination that diclosulam rapidly degrades in high pH substrates. *See* EPA, Diclosulam Fact Sheet at 290, *available at* www.epa.gov/opprd001/factsheets/appen_j.pdf (last visited Nov. 22, 2004).

EPA authorized DAS to employ this warning for Strongarm's label:

> ***Note:*** *Environmental and soil factors can influence the performance and selectivity of any herbicide treatment. . . . When emergence of the planted crop is delayed due to unusually cool and/or wet conditions, factors* ***such as pH****, disease, and nutrient deficiencies can contribute to reduced crop tolerance to a soil-applied herbicide.*

JA 86 (italics in original, bold emphasis added).

2. The legal claims at issue in this case arose from the poor harvests that some West Texas peanut farmers experienced in the fall of 2000. Extreme heat, a prolonged midseason drought, and heavy fall rains that delayed harvests until November and December made the 2000 growing season "a wreck" for many West Texas peanut farmers. Ron Smith, *2000 Crop "Challenge from Beginning to End,"* Southwest Farm Press (Dec. 21, 2000), *available at* http://southwestfarmpress.com/mag/farming_crop_challenge_beginning/index.html (last visited Nov. 22, 2004). A number of farmers in the area, however, blamed their disappointing harvests on their use of Strongarm, theorizing that Strongarm was inappropriate for use in local soils with a high pH content.

When DAS learned of this dissatisfaction, it retained independent agricultural consultants specializing in crop loss evaluations "to serve as neutral, third-party mediators to work to facilitate fair and mutually-agreeable resolutions of lost yield claims." JA 143. Every Texas peanut farmer who participated in this mediation process and who could demon-

strate any lost yields even potentially attributable to applications of Strongarm was compensated.[9]

Petitioners chose instead to threaten suit. In a series of virtually identical demand letters sent to DAS in the fall of 2001, growers asserted claims worth a total of more than $26 million. JA 33-48. To avoid the burden of defending against numerous individual suits in various locations, DAS filed this declaratory judgment action in district court, seeking to establish that petitioners' claims were legally and factually groundless. As relevant here, DAS maintained that petitioners' threatened claims for damages are preempted by FIFRA's preclusion of state authority to "impose or continue in effect any requirements for labeling and packaging in addition to or different from those required" under FIFRA itself. *See* 7 U.S.C. § 136v(b).

Petitioners subsequently filed counterclaims, alleging that "peanuts treated with Strongarm® did not grow properly, were stunted, did not properly develop foliage and delayed in maturing for harvest[,] resulting in increase[d] ex-

[9] Out of caution, DAS petitioned EPA for authority to use a supplemental label, in Texas and two neighboring States, which included a warning not to use Strongarm in soils with pH levels of 7.2 or greater. JA 181. Subsequent studies, however, indicated that DAS had probably overreacted in doing so. Those studies reported that observed peanut crop injury in West Texas soils was temporary and largely self-resolved before harvest, and that any reduced yields were associated only with preplant incorporation applications in soils with pH levels of 7.6 and higher. *See* JA 133 ("No injury was observed at harvest, and neither grade nor yield was affected by any herbicide treatment."), 135 ("At 118 DAT [day after treatment], all injury decreased to < 5% and yield was not affected by diclosulam PRE. . . . At 14 DAT, diclosulam applied POST at both rates injured peanut < 5% in all varieties and no injury was observed 90 DAT. Yield was not affected by diclosulam (POST)."), 137 (in soils with pH levels ranging from 7.6 to 8.2, some yield reduction was noted when Strongarm was applied preplant incorporated at one test site, but "[p]eanut grade was not affected by any treatment when compared to the nontreated check. . . . No differences were observed in yield or grade at Seminole [the other test site]."), 129 (while Strongarm applied preplant incorporated in soils with a pH of 7.6 produced reduced crop yields, "[a]ll other Strongarm treatments had < 3% injury at the end of the season").

pense and . . . in reduced profit from sale and harvest." JA 184. Attributing these damages to their use of Strongarm in soils with purportedly elevated pH levels, petitioners maintained that DAS should have alerted them that Strongarm was not suitable for use in such situations. Petitioners framed their complaint about the unsuitability of Strongarm in elevated-pH soils in various ways, including negligence in development and manufacturing, deceptive trade practices, breach of contract, breach of express and implied warranties, strict liability for defective design and manufacturing, fraud, and negligence in representations made concerning Strongarm. JA 183-193.

3. The district court ruled that nearly all of petitioners' claims are preempted by FIFRA and granted summary judgment for DAS. The court first held that FIFRA's preemption of state laws that impose different or additional labeling requirements encompasses state common-law claims that would have such an effect. *See* Pet. App. 24a-25a.

The court then concluded that all but one of petitioners' claims falls within the scope of FIFRA's preemption provision.[10] All of those claims, the district court concluded, chal-

[10] The one exception to the district court's preemption ruling concerned petitioners' allegations that, *after* petitioners began experiencing problems with their peanuts, DAS representatives falsely assured three of them that their peanuts would grow out of any problems caused by Strongarm and falsely promised to pay for losses and expenses caused by Strongarm. *See* JA 190. Those claims, the district court held, were not preempted by FIFRA, because the allegedly misleading statements did "not repeat any information on the Strongarm label." Pet. App. 29a. The district court also held, however, that those claims were barred as a matter of state law by the express limitation of remedies on the Strongarm label, which limited purchasers to a substitute product or the return of the purchase price. *See id.* at 29a-30a. DAS expressed its willingness to avoid further litigation on this point by depositing into the registry of the district court a sum equal to the price of the product that petitioners had purchased. Petitioners declined to accept that offer. Petitioners did not, however, appeal the district court's ruling that their claims based on allegedly post-sale statements by DAS representatives were barred as a matter of state law. *See* p. 50, *infra*.

lenge the sufficiency or accuracy of statements about Strongarm on the pesticide's label and therefore, if sustained, would impose requirements for the label in addition to or different from those required by federal law. Pet. App. 25a-30a. Although petitioners rested some of their claims on "off-label" statements allegedly made by DAS agents, the district court ruled that petitioners had failed to show that those statements differed in any material way from the contents of the Strongarm label. *Id.* at 25a, 28a. Thus, the court ruled, those claims also do nothing more than "challenge the Strongarm label." *Id.* Further, the district court ruled, petitioners' negligent design, manufacture, and testing claims amount in substance to challenges to the Strongarm label. *Id.* at 30a. Because petitioners insisted that, if the changes in the Strongarm label made in 2001 had been made in 2000, they would not have used the herbicide, the court concluded that petitioners' negligence claims were "in actuality . . . failure to warn claim[s]," and thus at bottom challenged the adequacy of warnings on the label. *Id.*

4. The court of appeals affirmed. Pet. App. 2a. The court of appeals agreed with the district court that, although FIFRA does not preempt common-law claims unconcerned with labeling, it does preempt state duties, including those based in common law, that "either directly or indirectly impose different labeling requirements." *Id.* at 11a. The court also rejected petitioners' contention that common-law claims based on product effectiveness fall outside FIFRA's preemption provision merely because EPA, as a matter of policy, generally refrains from assessing efficacy claims made by pesticide manufacturers in the registration process. As the court explained, "[t]he scope of FIFRA's preemption clause is defined by the simple text of § 136v(b)." *Id.* at 14a. "For a state to create a labeling requirement by authorizing a claim linked to the specifications of a label, even where the EPA has elected not to impose such labeling requirements, would clearly be to impose a requirement 'in addition to or different from those' required under FIFRA." *Id.* at 15a.

The court then examined, with respect to each of petitioners' claims, "whether a judgment against [DAS] would cause it to need to alter the Strongarm label." Pet. App. 16a. After independently reviewing the record, the court of appeals agreed with the district court that petitioners' breach of warranty, fraud, and deceptive trade practices claims are all preempted because "no evidence was presented demonstrating that the retailer statements deviated from the contents of the Strongarm label." *Id.* at 17a. The court did remark that "[d]efectively manufactured or designed products properly labeled under FIFRA are generally subject to state regulation." *Id.* at 18a. But, like the district court, it concluded that petitioners' particular defective-design claims are really "disguised claim[s] for failure to warn" and thus preempted. *Id.* Finally, the court held petitioners' negligence claims preempted because, "as a matter of Texas law," a negligent testing claim is but "a variation of an action for failure to warn," *id.* at 19a, and thus reduces once again to a claim that the Strongarm label was defective.[11]

SUMMARY OF ARGUMENT

FIFRA preempts state-law damages actions that would impose labeling duties different from or in addition to those established under FIFRA itself. The language, purposes, and legislative history of FIFRA make that clear, as do this Court's preemption decisions. Moreover, unlike preemption provisions in some other federal statutes, FIFRA does not make preemption turn on regulatory activity by the agency entrusted with administering the statute. Thus, petitioners' contention that FIFRA does not preempt claims related to efficacy because EPA has chosen to refrain from requiring

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[11] The court of appeals did not expressly address the district court's conclusion that petitioners' claims based on post-sale representations, though not preempted by FIFRA, were barred by state law. *See* p. 50, *infra*. In light of the court of appeals' apparent conclusion that all of petitioners' claims were preempted by federal law, DAS withdrew its funds from the district court registry (*see* p. 13 n. 10, *supra*), but remains ready to refund the purchase price to petitioners.

submission of efficacy data is incorrect. Petitioners' suggestion that their claims simply seek parallel remedies for violations of FIFRA's misbranding prohibition is equally groundless. Petitioners' interpretation would give juries in 50 States the authority to give content to FIFRA's misbranding prohibition, establishing a crazy-quilt of anti-misbranding requirements different from the one defined by FIFRA itself and intended by Congress to be interpreted authoritatively by EPA. Although petitioners package their claims variously in an effort to make them seem unrelated to labeling, all but one of their claims would clearly force DAS to alter Strongarm's FIFRA-approved label and therefore establish requirements for labeling in addition to and different from those mandated by FIFRA. While FIFRA's preemptive domain is not boundless, those claims squarely fall within it.

I. Section 136v(b) of Title 7 prohibits States from "impos[ing] or continu[ing] in effect[] any requirements for labeling or packaging in addition to or different from those required under" FIFRA itself. State-law damages actions that would have the effect of requiring manufacturers to alter pesticide labels impose labeling "requirements" in addition to or different from those required under FIFRA. As this Court has repeatedly recognized, the ordinary meaning of "requirements" includes state-law damages actions because, like positive enactments, they require compliance with state-law duties. Preemption is particularly warranted given FIFRA's focus on uniformity of pesticide labeling. The legislative history of FIFRA confirms this point, as does a tidal wave of lower-court decisions holding that FIFRA preempts state-law damages actions based on labeling.

II. FIFRA does not exempt damages actions related to efficacy from its preemption of label-related lawsuits. Section 136v(b) says just the opposite: it mandates that "*any*" state-law labeling requirement is preempted, whether it concerns efficacy or not. The words of § 136v(b) also make plain that its preemptive effect does not occur only when EPA has exerted regulatory authority. FIFRA preempts

any state-law requirements beyond those "required *under this subchapter*," the subchapter being the statute itself. FIFRA thus stands in contrast with other federal statutes, including ones administered by EPA, in which Congress has indicated that the statute's preemptive effect depends on regulatory activity. In any case, EPA retains both the discretion to require submissions about efficacy and the authority to take action against inaccurate statements concerning efficacy, and has promulgated numerous requirements relating to labeling.

III. Petitioners' contention that their claims are simply state-law remedies for violations of FIFRA's misbranding prohibition is inconsistent with the centralized administrative and enforcement mechanism set up by Congress, which intended that FIFRA's misbranding provisions would be enforced exclusively by the federal government. Congress considered and rejected a private right of action to enforce FIFRA's misbranding prohibition precisely to ensure centralized enforcement of the law. Petitioners' interpretation would achieve just the opposite. It would leave to juries in 50 States the discretion to give content to FIFRA's misbranding prohibition, thus establishing a patchwork of anti-misbranding requirements different from the one defined by FIFRA itself and intended by Congress to be interpreted authoritatively by the EPA.

IV. All but one of petitioners' claims are in substance label-related and so are preempted by FIFRA. This does not mean that all claims based on pesticide defects are preempted; rather, this conclusion stems from the substance of petitioners' claims and their litigation decisions. Petitioners' real complaint is not that Strongarm suffers from some defect that better manufacturing or testing would have revealed or that makes the pesticide unreasonably dangerous. Rather, their complaint is that DAS allegedly knew Strongarm was unsuitable for use in high pH soils but failed to tell them so. Thus, their grievance is not with the product, but with the information DAS provided about the product. Giv-

ing petitioners a common-law remedy would require DAS to change that information by changing the label.

ARGUMENT

I. FIFRA Preempts State-Law Damages Actions As Well As Positive State Enactments That Would Impose Additional Or Different Labeling Duties

A. The Text Of 7 U.S.C. § 136v(b) Encompasses Common-Law Labeling Claims

Petitioners principally argue that FIFRA's preemption provision, 7 U.S.C. § 136v(b), must be read to reach only positive enactments of state law that would impose labeling obligations different from, or in addition to, those required under FIFRA, and not common-law duties that would have exactly the same effect, but would be enforced through private damages actions. That contention cannot be squared with the text, structure, purposes, or background of FIFRA, or with this Court's decisions that have consistently recognized the practical equivalence, for preemption purposes, of damages actions and positive enactments.

1. Because Congress expressly addressed preemption in § 136v(b), "the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent." *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658, 664 (1993). That provision states:

> **(b) Uniformity**
>
> [A] State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

The plain meaning of the operative words of § 136v(b)—particularly the use of the term "requirements" and the explicit call for "uniformity"—indicates that state-law suits fall within the provision's preemptive scope if they would have the effect of imposing additional or different labeling requirements on pesticide manufacturers.

This Court has twice examined statutory provisions that, like § 136v(b), preempt state-law "requirements" in the context of a federal regulatory scheme. *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992); *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996). In *Cipollone*, the Court considered the preemptive reach of § 5(b) of the Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 ("Cigarette Act"). Like FIFRA, the labeling provisions of the Cigarette Act were the product of Congress's judgment that facilitation of commerce and safety concerns required the elimination of "diverse, nonuniform, and confusing . . . labeling." *Cipollone*, 505 U.S. at 511 n.5 (quoting 15 U.S.C. § 1331 (1982)). In terms materially indistinguishable from § 136v(b), the Cigarette Act conveyed that intent by providing: "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." *See id.* at 515.

Six Justices construed that language as "plainly reach[ing] beyond" positive enactments to encompass common-law suits. *Cipollone*, 505 U.S. at 521 (plurality); *see id.* at 548–549 (Scalia, J., joined by Thomas, J., concurring in the judgment in part and dissenting in part). As those Justices emphasized, "[t]he phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules." *Id.* at 521 (plurality); *see id.* at 548-549 (Scalia, J.) ("the language of the [Cigarette] Act plainly reaches beyond [positive] enactments") (internal quotation marks omitted). That interpretation of the Cigarette Act's preemption provision, the lead opinion explained, was also consistent with the Court's traditional understanding of common-law actions: "[C]ommon-law damages actions . . . are premised on the existence of a legal duty, and it is difficult to say that such actions do not impose 'requirements or prohibitions.' " *Id.* at 522 (plurality). The plurality distinguished the Cigarette Act's predecessor, which was held not to preempt common-

law claims, on the ground that the earlier law did not use the term "requirements" and preempted only "statements" imposed under state law. As the plurality explained, "[w]hereas the common law would not normally require a vendor to use any specific *statement* on its packages or in its advertisements, it is the essence of the common law to enforce duties that are . . . affirmative *requirements*." *Id.*[12]

A majority of Justices confirmed in *Medtronic* that the term "requirements," when used in a preemption provision, encompasses common-law damages actions. The statute at issue in that case, the Medical Device Amendments of 1976 (MDA), contained an express preemption provision that, while different in important ways from § 136v(b), *see* pp. 26-27, 33-34, *infra*, also displaced state-law "requirements." Although a majority of the Justices held that the particular claims at issue in that case were not preempted, at least five Justices concluded that "the term 'requirement' encompasses state common-law causes of action." *Medtronic*, 518 U.S. at 512 (O'Connor, J., concurring in part and dissenting in part); *see id.* at 503-505 (Breyer, J., concurring in part and concurring in the judgment). As Justice O'Connor, joined by the Chief Justice, Justice Scalia, and Justice Thomas, explained, "state common-law damages actions operate to require manufacturers to comply with common-law duties." *Id.* at 510. Justice Breyer, whose concurring opinion is controlling in *Medtronic*, *see Marks* v. *United States*, 430 U.S. 188, 193-194 (1975), agreed that "[o]ne can reasonably read the word 'requirement' as including the legal requirements that grow out of the application, in particular cases, of a State's tort law." 518 U.S. at 504.

[12] Moreover, the plurality in *Cipollone* concluded that "requirements" included common-law actions even in the face of a provision, carried over from the predecessor statute, indicating that Congress's purpose was to preempt state "regulations," a narrower term referring to positive enactments. *See* 505 U.S. at 519 (relying on statement of purpose to limit preemptive scope of predecessor statute). FIFRA contains no such indication of congressional purpose to preempt only positive state enactments, and so the case for preemption is yet stronger here.

This Court has thus recognized that for preemption purposes, Congress's use of the term "requirements" signals an intent to preempt not only positive enactments but also state common-law suits. That recognition is consistent with a long line of cases confirming that "the effects of [state positive] regulation and [a] state tort suit are identical," *Medtronic*, 518 U.S. at 504 (Breyer, J.), because both "require" compliance with state-law duties in the ordinary sense of that term. *See CSX*, 507 U.S. at 664 (holding that "[l]egal duties imposed . . . by the common law fall within the scope of" the terms "law, rule, regulation, order, or standard" or other "State requirements"); *International Paper Co.* v. *Ouellette*, 479 U.S. 481, 494 (1987) (holding state-law nuisance suits, as well as positive enactments, preempted because such suits "could *require* the source to cease operations by ordering immediate abatement" and thus would allow states to "do indirectly what they could not do directly") (emphasis added); *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 323 (1981) (concluding that "common-law obligations" are intended to "use the threat of damages to *require*" a party to conform) (emphasis added); *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 244 (1959) (describing the duties underlying state common-law suits as "requirements imposed by state law"); *cf. Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 881 (2000) (holding state tort suit preempted because it "would have *required* manufacturers of all similar cars to install airbags rather than other passive restraint systems").

According the term "requirements" its ordinary reading is particularly appropriate in the context of a federal enactment that, like § 136v(b), is expressly designed to achieve "uniformity" in national standards. "This policy [of uniformity] by itself favors pre-emption of state tort suits, for the rules of law that judges and juries create or apply in such suits may themselves similarly create uncertainty and even conflict, say, when different juries in different States reach different decisions on similar facts." *Geier*, 529 U.S. at 871. In the context of pesticide labels, the danger of disuniformity is particularly serious, because labels frequently ad-

vise users about many different matters—including the proper method of application, the strength of the mixture to be used, and the timing of application. All of those matters must be balanced in determining the most effective way of placing users on notice of the particular characteristics of the pesticide. A jury verdict finding the label defective in some fashion would disrupt that balance. If a jury were to conclude, for example, that a label did not contain sufficiently prominent warnings about efficacy, the manufacturer would presumably have to change its labels to give greater emphasis to efficacy—but such emphasis could comparably diminish the prominence of the manufacturer's warnings about safety on the label, perhaps leading in turn to duty-to-warn suits on the ground that the label's safety warnings were insufficient.

Preemption under FIFRA cannot be avoided on the supposition that a pesticide manufacturer would continue to use one uniform federal label and elect to pay judgments arising from state-law damages actions, rather than amend its label to conform to various state common law duties. "[T]his Court's pre-emption cases ordinarily assume compliance with the state-law duty in question." *Geier*, 529 U.S. at 882.[13] Accordingly, a common-law obligation enforced through state tort suits plainly requires or "compels [a party] to adopt different . . . standards" from those of federal law. *Ouellette*, 479 U.S. at 495. "[T]o leave the States free to regulate conduct" through such means therefore "involves too great a danger of conflict between" the uniformity intended by Congress and "requirements imposed by state law." *Garmon*, 359 U.S. at 244; *see Kalo Brick*, 450 U.S. at 323 (state-law tort suits "could hardly be more at odds with the uniformity contemplated by Congress").[14]

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[13] One case where the Court clearly rejected this supposition is, of course, *Cipollone*, where this very argument was put forward by Justice Blackmun, in dissent. *See* 505 U.S. at 536-538.

[14] Petitioners seek to draw support (Br. 20-21 n.8) from *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984), and *Goodyear Atomic Corp.* v. *Miller*, 486 U.S. 174 (1988), in arguing that Congress might have intended to preclude States from imposing only positive label requirements, and not also functionally identical common-law labeling duties. Both of those decisions involved statutory schemes quite different from FIFRA. In *Silkwood*, the Court concluded that, although the federal Atomic Energy Act precluded States from directly imposing safety standards at nuclear power plants, it did not preclude private tort actions arising out of the unsafe operation of such plants. Critical to the Court's conclusion, however, was the existence of another federal statute, the Price-Anderson Act, which expressly contemplated the existence of private tort actions, *see* 464 U.S. at 623-626, and indeed the Court noted that, in the absence of the Price-Anderson Act, the Atomic Energy Act "arguably would disallow resort to state-law remedies by those suffering injuries from radiation in a nuclear plant," *id.* at 623. No comparable federal statute in this case contemplates the continued existence of private state-law tort suits involving pesticide labels. *Goodyear* did not involve a statutory preemption provision at all; rather, the Court concluded that a federal statute *authorizing* the application of state workers' compensation laws to federal facilities included authority to make a supplemental award based on the employer's violation of a specific state safety regulation. 486 U.S. at 182-184.

2. In an effort to avoid the force of these decisions, petitioners put forward a contrived structural argument based on the supposed interplay between § 136v(b) and its surrounding provisions. Those arguments fall wide of the mark.

Petitioners characterize § 136v(b) as an exception to § 136v(a), which reaffirms state authority to "regulate" the sale and use of pesticides. *See* Pet. Br. 17-18. Petitioners suggest that the "requirements" preempted under § 136v(b) must be understood as a subset of the state "regulations" permitted under § 136v(a). Because (petitioners argue) the "regulations" authorized in § 136v(a) refer only to positive enactments, so too must the "requirements" preempted in § 136v(b). Of course, this argument turns on the construction of "regulation"—not "requirement." But this case is about the meaning of the term "requirement" in § 136v(b), not the meaning of "regulation" in § 136v(a).

In any event, petitioner's syllogism fails in several respects. First, and most fundamentally, there is no basis to conclude that Congress structured § 136v(b) as an exception to § 136v(a). This Court has made clear that § 136v(a) does

not function as a restatement of all permissible state authority over pesticides; even if Congress had never enacted § 136v(a), the States would have retained all regulatory authority not preempted by FIFRA (either expressly or because of actual conflicts with federal law). *See Mortier*, 501 U.S. at 614 ("The specific grant of authority in § 136v(a) . . . does not serve to hand back to the States powers that the statute had impliedly usurped."). Rather, § 136v(a) preserves for the States regulatory authority that "might otherwise have been pre-empted through actual conflicts with federal law." *Id.* at 607. But there is no basis to conclude that § 136v(b) functions only as an exception to that specific state authority conferred by § 136v(a). Even petitioners have never suggested that § 136v(b) preempts only state authority to enact positive labeling requirements that would actually conflict with federal labeling requirements. Indeed, the text of § 136v(b) would refute such a reading, because it precludes state labeling requirements that are "in addition to," not just in conflict with, federal requirements for labeling. Rather, § 136v(b) clearly preempts all state labeling requirements, even if they would not be preempted under "implied preemption" or "conflict" preemption analysis. The only question is whether the preempted "requirements" include those imposed by state common law.

Second, the assertion that Congress intended the word "requirements" to denote a subset of the universe of state "regulations" is inherently implausible. This Court's decisions make clear, to the contrary, that "regulations" is the narrower of the two terms. The term "regulation," like "statute," "implies a discreteness . . . that is not present in the common law." *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 63 (2002). "Requirement," by contrast, "sweeps broadly and suggests no distinction between positive enactments and common law." *Cipollone*, 505 U.S. at 521 (plurality). "Requirements," in short, is "obviously broader" than "regulations," *id.* at 523, and nothing in § 136v justifies the diametrically opposite conclusion put forward by petitioners.[15]

Third, petitioners fail to explain why Congress used the term "requirements," rather than "regulations," in § 136v(b). If Congress had understood the matters preempted by § 136v(b) to be a subset of state "regulations" preserved by § 136v(a), then it would have been much more straightforward for Congress to have used the term "regulations" again in §136v(b)—not "requirements." The fact that Congress used the two different terms in neighboring provisions strongly indicates that Congress meant different things by them. *See Barnhart* v. *Sigmon Coal Co.*, 534 U.S. 438, 454 (2002); *see also United States* v. *Hohri*, 482 U.S. 64, 70 (1987) ("[W]e find it difficult to assume that the variation within the same subsection was inadvertent.").

Nor can any significant inference be drawn from the fact that Congress referred in § 136v(b) to the federal labeling provisions under FIFRA as the "requirements" that are "required under this subchapter." Because the term "requirements" is broader than "regulations," it was entirely reasonable for Congress to use the broader term to refer both to federal positive-law enactments and all preempted state-law obligations, whether imposed by positive law or common law. That Congress broadly described all rules imposed by federal law as "requirements," both in § 136v(b)

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[15] Common dictionary definitions in existence at the time of the 1972 amendments confirm that the terms "require" and "requirement" are considerably broader than the terms "regulate" and "regulation." *E.g.*, *Webster's Seventh New Collegiate Dictionary* 722, 729 (7th ed. 1970) (defining "regulation" to mean "2a: an authoritative rule dealing with details of procedure b: a rule or order having the force of law issued by an executive authority of a government," but defining "require" to mean "2a: to call for as suitable or appropriate b: to demand as necessary or essential: NEED, WANT 3: to impose a compulsion or command on: COMPEL," and defining "requirement" to mean to "a: something wanted or needed: NECESSITY"); *Black's Law Dictionary* 1468 (4th ed. 1968) (defining "require" to mean "[t]o direct, order, demand, instruct, command, claim, compel, request, need, exact").

and elsewhere in FIFRA, in no way narrows that term's ordinary meaning. Indeed, a similar argument failed to persuade a majority of this Court in *Medtronic*, which (as the plurality pointed out, *see* 518 U.S. at 489), also involved a statute that used the term "requirements" to refer to both federal and state law.

3. Petitioners make great efforts to obtain support from the plurality opinion in *Medtronic*. Even if one were to assume that the plurality opinion in that case governed (which it does not, *see* pp. 20-21, *supra*), it would lend little support to petitioners, for the statutory scheme at issue there was significantly different from FIFRA. The provision at issue in *Medtronic*, 21 U.S.C. § 360k, preempted any state-law "requirement" that was applicable to any medical device for which there was also a device-specific federal requirement imposed by regulation. That preemption provision was not limited to a discrete subject such as labeling, as under FIFRA or the Cigarette Act examined in *Cipollone*. Indeed, the contention in *Medtronic* was that the statute preempted "any and all common-law claims brought by an injured plaintiff." 518 U.S. at 486 (plurality). Adoption of that position would have "effectively precluded state courts from affording state consumers any protection from injuries" from medical devices, *id.* at 487—a far broader reach than the preemption provision at issue here, which covers only labeling requirements.[16] The much narrower scope of the preemption provision in FIFRA provides greater confidence that Congress intended to reach common-law duties as well as positive enactments.

[16] *See also* 518 U.S. at 486 (plurality) (suggesting that Medtronic's construction would "grant complete immunity" to medical device industry); *id.* at 488 (distinguishing *Cipollone* on the ground that the preemption provision in the Cigarette Act "was targeted at a limited set of state requirements" and "giving the term 'requirement' its widest reasonable meaning [in *Cipollone*] did not have nearly the pre-emptive scope nor the effect on potential remedies" that a similar approach would have under the MDA).

Second, the result in *Medtronic* turned in large part on the "unique role" of the Food and Drug Administration under the MDA. *See* 518 U.S. at 496 (plurality), 506-507 (Breyer, J.). Congress "explicitly delegated" to FDA the authority to exempt state regulations from the preemptive effect of the MDA, and that process "necessarily require[d] the FDA to assess the pre-emptive effect that the [MDA] and its own regulations will have on state laws." *Id.* at 496 (plurality). FDA, in turn, promulgated a regulation providing that state laws of general applicability are not preempted by the MDA. *See id.* at 498 & n.18. This "congressional grant of authority" to FDA to determine the scope of preemption led the plurality and Justice Breyer to give "substantial weight" to FDA's conclusion that the claims at issue in that case were not preempted. *Id.* at 496 (plurality); *see id.* at 505-507 (Breyer, J.). Here, by contrast, preemption does not turn on what EPA has or has not done; rather, the statute itself dictates the scope of preemption of state law—any "requirements for labeling or packaging in addition to or different from those required under [FIFRA]." 7 U.S.C. § 136v(b). *See also* pp. 31-36, *infra*. And to the extent that the agency's position on preemption does matter here, it supports respondent, for EPA agrees that § 136v(b) preempts common-law labeling claims.

4. Finally, it bears emphasis that all nine federal courts of appeals that have addressed FIFRA preemption since *Cipollone* and *Medtronic* have concluded that § 136v(b) preempts common-law labeling claims.[17] The highest courts of

[17] *See Lowe's Home Ctrs., Inc.* v. *Olin Corp.*, 313 F.3d 1307 (11th Cir. 2002); *Netland* v. *Hess & Clark, Inc.*, 284 F.3d 895 (8th Cir. 2002); *Nathan Kimmel, Inc.* v. *DowElanco*, 275 F.3d 1199 (9th Cir. 2002); *Ruiz-Guzman* v. *Amvac Chem. Corp.*, No. 98-35088, 243 F.3d 549, 2000 WL 1763212 (9th Cir. Nov. 28, 2000); *Hawkins* v. *Leslie's Pool Mart, Inc.*, 184 F.3d 244 (3d Cir. 1999); *Andrus* v. *AgrEvo USA Co.*, 178 F.3d 395 (5th Cir. 1999); *Lescs* v. *William R. Hughes, Inc.*, No. 97-2278, 168 F.3d 482, 1999 WL 12913 (4th Cir. Jan. 14, 1999); *National Bank of Commerce* v. *Dow Chem. Co.*, 165 F.3d 602 (8th Cir. 1999); *Kuiper* v. *American Cyanamid Co.*, 131 F.3d 656 (7th Cir. 1997); *Rodriguez* v. *American Cyanamid Co.*, No. 96-15752, 116

at least 18 states have agreed. *See* Br. in Opp. 16-17 (collecting cases). In another nine States, intermediate courts of appeal have also adopted this construction. *See id.* at 17. Only one state supreme court and one state intermediate appellate court have disagreed. *Id.* "The very strength of this consensus is enough to rule out any serious claim of ambiguity." *General Dynamics Land Sys., Inc.* v. *Cline*, 124 S. Ct. 1236, 1244-1245 (2004) (footnote omitted). And even if § 136v(b) were arguably susceptible to petitioners' construction, the Court should instead adopt the "longstanding, consistent interpretation" of § 136v(b) that has prevailed in the lower courts. *See, e.g., Brogan* v. *United States*, 522 U.S. 398, 420 n.3 (1998) (Stevens, J., dissenting).

B. The Legislative History Of FIFRA Confirms The Plain Meaning Of § 136v(b)

Because the text of § 136v(b) clearly encompasses common-law claims, this Court "must give effect to this plain language unless there is good reason to believe Congress intended the language to have some more restrictive meaning." *Shaw* v. *Delta Air Lines, Inc.* 463 U.S. 85, 97 (1983). Petitioners attempt to justify such a departure based on FIFRA's legislative history, but that legislative history only confirms Congress's broad preemptive intent.

Petitioners' principal argument is that common-law claims for crop damage were so well established by 1972, when Congress enacted § 136v(b), that Congress should not

F.3d 485, 1997 WL 306430 (9th Cir. June 5, 1997); *Grenier* v. *Vermont Log Bldgs., Inc.*, 96 F.3d 559 (1st Cir. 1996); *Welchert* v. *American Cyanamid Inc.*, 59 F.3d 69 (8th Cir. 1995); *Taylor AG Indus.* v. *Pure-Gro*, 54 F.3d 555 (9th Cir. 1995); *Lowe* v. *Sporicidin Int'l*, 47 F.3d 124 (4th Cir. 1995); *Bice* v. *Leslie's Poolmart, Inc.*, 39 F.3d 887 (8th Cir. 1994); *MacDonald* v. *Monsanto Co.*, 27 F.3d 1021 (5th Cir. 1994); *Worm* v. *American Cyanamid Co.*, 5 F.3d 744 (4th Cir. 1993); *King* v. *E.I. du Pont de Nemours & Co.*, 996 F.2d 1346 (1st Cir. 1993); *Shaw* v. *Dow Brands, Inc.*, 994 F.2d 364 (7th Cir. 1993); *Papas* v. *Upjohn Co.*, 985 F.2d 516 (11th Cir. 1993); *Arkansas-Platte & Gulf P'ship* v. *Van Waters & Rogers, Inc.*, 981 F.2d 1177 (10th Cir.); *see also Oken* v. *Monsanto Co.*, 371 F.3d 1312 (11th Cir. 2004), *petition for cert. filed*, 73 U.S.L.W. 3287 (U.S. Oct. 24, 2004) (No. 04-579).

be deemed to have preempted such claims in silence. The mere fact that state law was settled in 1972 could hardly defeat preemption, however, because Congress expressly precluded States from either imposing *or* "contin[uing] in effect" any labeling requirement. 7 U.S.C. § 136v(b). Moreover, reports of common-law labeling suits before 1972 would have simply confirmed to Congress the very point being made here—namely, that such state-law actions could affect the content of the federally-approved pesticide label.[18] Those suits established that pre-1972 federal law set only a floor for labeling, and did not preclude the States from requiring more. But that is precisely the regime Congress abolished in § 136v(b). It is thus not surprising that the relevant Committee Reports accompanying §136v(b) described its preemptive scope in absolute terms that brook no distinction between positive and common law.[19]

Furthermore, Congress considered, but rejected, a provision that would have given petitioners exactly what they effectively seek now—a clause saving common-law claims. In 1972, a subcommittee of the Senate Agriculture Committee proposed an amendment to legislation then under consideration that would have both added a federal citizen's-suit provision and preserved the right of individuals to pursue

[18] *See Hubbard-Hall Chem. Co.* v. *Silverman*, 340 F.2d 402, 405 (1st Cir. 1965) (upholding jury verdict "that a warning even if it were in the precise form of the label submitted to the Department of Agriculture" did not discharge manufacturer's common-law duty to warn); *Griffin* v. *Planters Chem. Corp.*, 302 F. Supp. 937, 944 (D.S.C. 1969) ("Aside from the requirements set forth for the label by the Secretary of Agriculture, he had a duty to use a label, or furnish a warning commensurate with the danger. . . . The duty of defendant is over and above the requirements of the Secretary of Agriculture.").

[19] *See* H.R. Rep. No. 92-511, at 1-2 ("State authority to change Federal labeling and packaging is completely preempted."); *id.* at 16 ("[T]he Committee has adopted language which is intended to completely preempt State authority in regard to labeling and packaging."); S. Rep. No. 92-838, pt. I, at 30 ("Subsection (b) preempts any State labeling or packaging requirements differing from such requirements under the Act").

common-law claims. Later that year, the Senate Commerce Committee proposed an expanded version of the same amendment, also containing a broad savings clause for common-law claims. A version of the savings clause ultimately passed the Senate, but it was deleted by the Conference Committee. *See* p. 4, *supra*. The Conference Committee's rejection of this provision "strongly militates against the judgment that Congress intended a result that it expressly declined to enact." *Gulf Oil Corp.* v. *Copp Paving Co.*, 419 U.S. 186, 200 (1974).

The reasons for Congress's rejection of a *federal* private right of action to enforce FIFRA—specifically including its labeling requirements—are also probative here. As the Senate Agriculture Committee observed, such a cause of action could "encourage suits by professional litigants and interfere with the orderly administration of the law." S. Rep. No. 92-838, pt. II, at 39. Congress's concern for the "orderly administration" of FIFRA, including its labeling requirements, underscores its wish to place pesticide labels under the exclusive jurisdiction of the expert agency, EPA. Common-law suits based on labeling, no less than state positive regulations, undermine this congressional policy.

Congress has never budged from this stance of broad preemption of state labeling requirements, even though it has revisited FIFRA numerous times. In 1978, for example, when Congress granted EPA authority to waive its review of efficacy data, Congress reenacted FIFRA's preemption clause with only immaterial changes. *See* p. 3 n.3, *supra*. In 1996, Congress enacted the Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489, which amended FIFRA but left § 136v(b) untouched. By that time, FIFRA preemption jurisprudence was so well-established that it was "described as a 'tsunami' wave of precedent." *Hue* v. *Farmboy Spray Co.*, 896 P.2d 682, 691 (Wash. 1995) (collecting authorities). The accumulation of cases giving effect to § 136v(b)'s broad text has continued unabated (*see* pp. 27-28, *supra*), but Congress has not revised that provision even as it has modified other aspects of FIFRA, as recently as January 2004. *See* Pesticide Registration Improvement Act of 2003, Pub. L. No. 108-199, § 501, 118 Stat. 3, 419 (2004). The legislative history of FIFRA thus gives no cause for doubt that § 136v(b) precludes common-law labeling suits.

II. CONGRESS DID NOT EXEMPT CLAIMS RELATING TO EFFICACY FROM PREEMPTION UNDER FIFRA

Petitioners argue in the alternative that, even if § 136v(b) preempts some state-law labeling claims, it does not extend to suits challenging statements regarding product efficacy. Noting that EPA commonly waives review of efficacy data in the registration process, petitioners contend (Br. 32) that "there is no EPA action, rule, or decision that would conflict with the farmers' suit" and thus no basis for preemption of these claims. This argument reflects a basic misconception of the way in which preemption under FIFRA operates and, in any event, fails on its own terms.

A. Preemption Under FIFRA Arises From The Statute—Not From The Agency's Exercise Of Its Regulatory Authority

1. In seeking to carve out labeling requirements related to efficacy claims from the preemptive scope of § 136v(b), petitioners argue that a state labeling requirement is not preempted if EPA has not exercised its own regulatory authority in the particular area covered by that state requirement. Thus, petitioners submit, because EPA has not required efficacy statements on pesticide labels, the States are free to do so. That approach to preemption, however, is quite unlike the one taken by Congress in FIFRA.

Unlike some other statutes, in which preemption occurs only when the agency has exerted regulatory authority in the same area (*see, e.g., Freightliner Corp.* v. *Myrick*, 514 U.S. 280 (1995)), FIFRA defines its preemptive domain by reference to the statute itself. Section 136v(b) preempts "any requirement for labeling or packaging" that is "in addition to or different from those required *under this subchap-*

ter" (emphasis added). "[T]his subchapter" refers to FIFRA itself.[20] As petitioners recognize (Br. 18, 23, 29), requirements for labeling "under this subchapter" are set forth elsewhere in FIFRA—particularly in the definition of a "misbranded" pesticide, which includes specific directions about what may and may not appear on the label. 7 U.S.C. § 136(q); *see* 40 C.F.R. pt. 156; 49 Fed. Reg. 37,960, 37,960 (1984) ("The statutory standard that is the basis for Agency regulation of pesticide labeling is contained in section 2(q) of FIFRA, which defines a 'misbranded' pesticide and enumerates specific labeling deficiencies that constitute misbranding"). Nothing in § 136v(b) suggests that preemption comes into play only when EPA exerts regulatory authority in a particular area.[21]

In short, § 136v(b) provides that *any* state-law "requirements" that are additional to or different from those imposed by FIFRA itself are preempted. This straightforward reading of § 136v(b) is confirmed by a comparison of that provision to other statutes in which Congress has expressed its intent to render the scope of preemption dependent on the existence of applicable regulations. Most notably, in the Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489—which amended FIFRA but left FIFRA's preemptive scheme undisturbed, *see* p. 30, *supra*—Congress provided that "no State or political subdivision may establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food *if a qualifying Federal determination applies* to the presence of such pesticide chemical residue in or on such food, unless such State

[20] *See* 7 U.S.C. §§ 136 (setting forth definitions that apply to "this subchapter"), 136a (prohibiting sale of any pesticide "that is not registered under this subchapter"), 136j(a)(2) (prohibiting alteration of "any labeling required under this subchapter").

[21] EPA agrees with this reading of the statute: "[S]tate tort claims based on a lack of efficacy that would, in effect, require the registrant to add to or subtract from the pesticide label in order to avoid liability are preempted regardless of whether EPA receives or reviews efficacy data in a particular case." U.S. Br. 17 n.6 (May 2004) (filed at petition stage).

regulatory limit is identical" to the federal determination. 21 U.S.C. § 346a(n)(4) (emphasis added). Similarly, in another EPA-administered preemptive regime, the Toxic Substances Control Act, Congress prescribed that "*if the Administrator requires by a rule* promulgated under . . . this title the testing of a chemical substance or mixture, no State or political subdivision may, after the effective date of such rule, establish or continue in effect a requirement" on the same subject. 15 U.S.C. § 2617(2)(a)(A)-(B) (emphasis added).[22] These examples show that Congress is fully cognizant of the difference between preemption that occurs only once an agency has acted and preemption that derives from the statute itself—and that § 136v(b) is clearly an example of the latter.

For that reason, petitioners' reliance on *Medtronic* is again misplaced. The statute at issue in *Medtronic* explicitly tied its preemptive effect to the existence of "applicable" federal requirements. *See* 21 U.S.C. § 360(k)(a) ("[No state] may establish or continue in effect with respect to a device intended for human use any requirement—which is different from, or in addition to, any requirement *applicable under this subchapter to the device*") (emphasis added). "[P]reemption under the MDA d[id] not arise directly as a result of the enactment of the statute"; rather, that provision preempted state law "only to the extent the FDA ha[d] promulgated a relevant federal 'requirement.' " *Medtronic*, 518 U.S. at 495 (plurality). The MDA itself therefore re-

[22] Other examples abound. *See, e.g.*, Federal Railroad Safety Act, 49 U.S.C. § 20106 ("A State may adopt or continue in force any law, rule, regulation, order, or standard relating to railroad safety or security *until the Secretary . . . prescribes a regulation or issues an order covering the subject matter of the State requirement.*" (emphasis added)); Federal Motor Vehicle Safety Act, 15 U.S.C. § 1392(d) ("*Whenever a Federal motor vehicle safety standard established under this subchapter is in effect*, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, . . . any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard." (emphasis added)).

quired analysis as to whether particular state-law claims overlapped with agency action. In this case, by contrast, the preemptive effect of § 136v(b) arises from the statute itself, not the exercise of agency regulatory authority. Thus, in this case, as in *Cipollone*, "the territory exclusively occupied by federal law [i]s defined in the text of the statute itself." *See id.* at 489 n.9 (plurality) (discussing *Cipollone*).[23]

2. Congress's decision in 1978 to provide for EPA's selective waiver of efficacy review in the pesticide registration process cannot be construed as creating an implied exception to the plain text of § 136v(b). When Congress expressly granted EPA that discretionary authority, it did not remove product efficacy from EPA's purview; rather, it simply allowed the "Administrator [to] waive, *at his discretion*, data requirements pertaining to the efficacy of a pesticide" during initial registration and to "invoke efficacy requirements if he believed that they were necessary to assure the quality of product or to protect consumers." S. Rep. No. 95-334, at 9 (emphasis added). Moreover, EPA's authority over statements relating to efficacy remains inherent in EPA's authority to proceed against any pesticides that are "misbranded." *See* pp. 8-9, *supra*.

That Congress did not intend the efficacy-waiver amendments to limit § 136v(b)'s preemptive effect is confirmed by the history of that provision. In 1978, at the same time Congress granted EPA permission to waive efficacy review, Congress *reenacted* § 136v(b) with a single technical change and left the provision otherwise undisturbed. *See* Pub. L. No. 95-396, § 22, 92 Stat. 819, 835 (1978); H.R. Rep. No. 95-663, at 36 (1977) ("The section restates section 24(b) virtually as it now reads in FIFRA."). In fact, in the same amendments, Congress rejected proposed revisions that would have narrowed the scope of the preemption clause by prohibiting States "only from changing the approved *label*, rather than the labeling, of a registered pesticide product." S. Rep. No. 95-334, at 84; H.R. Rep. No. 95-1560, at 50 (1978). Congress has subsequently declined to revise § 136v(b) in response to decisions holding that § 136v(b) preempts labeling-based efficacy claims, and the only material change to that provision occurred in 1988, when Congress inserted the section header "Uniformity"—thus underscoring the importance of preemption in this context. *See* Pub. L. No. 100-532, § 801(m)(2), 102 Stat. 2654, 2682 (1988); *Geier*, 529 U.S. at 871.

3. Even if EPA regulations were deemed relevant to § 136v(b)'s scope—because, for example, the phrase "under this subchapter" were construed as referring to both FIFRA and its implementing regulations—such a conclusion would *extend*, not limit, that provision's preemptive effect. Thus, if EPA had determined not to exercise its regulatory authority under FIFRA to impose a particular labeling requirement, that would be a basis for finding the same requirement under state law preempted—not, as petitioners suggest, for finding it not preempted—because the requirement would clearly be "in addition" to any requirement "under" FIFRA (including EPA regulations thereunder). The same would be true if Congress had *prohibited* EPA from imposing a particular label requirement; the same requirement, if imposed by state law, would be "in addition" to the requirements "under" FIFRA.

Accordingly, a state-law labeling requirement based on pesticide efficacy—no more or less than a state-law re-

[23] FIFRA's preemptive scope cannot be tied to particular data submissions, because the Act itself does not impose data submission requirements on registrants, instead authorizing EPA to develop its own data submission requirements. *See* p. 4, *supra*; *see also* Pub. L. No. 92-516, § 3(c), 86 Stat. 973, 979-980 (1972) (granting the EPA discretion to "publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide"). The EPA in fact demands extensive data to support label claims, 40 C.F.R. pt. 158, but it does so as a result of agency implementation, not congressional mandate. Were this Court to create an exception to FIFRA preemption based on EPA's deferral of data submissions or the agency's exercise of its discretion to waive review of efficacy data in the initial registration process, EPA could become embroiled in litigation involving FIFRA-regulated products as litigants attempt to discover the quantity and quality of the data EPA reviewed, and to discover the intensity of agency scrutiny of that data.

quirement based on any other subject—falls within FIFRA's preemptive domain. Petitioners are flatly incorrect in arguing (Br. 30) that if "FIFRA no longer imposes a duty on EPA to evaluate the efficacy of any federally-registered pesticide, liability for the farmers' claims imposes no labeling requirements 'in addition to or different from' those in FIFRA." To the contrary, if federal law requires nothing, but state law requires something, that state-law-required something is both "in addition to" and "different from" the federal requirement. Thus, the court of appeals' reasoning was clearly correct: "For a state to create a labeling requirement by authorizing a claim linked to the specifications of a label, even where the EPA has elected not to impose such requirements, would clearly be to impose a requirement 'in addition to or different from those' required under FIFRA." Pet. App. 15a.

B. Petitioners' Claims Are Also Preempted Under Implied Conflict Principles

Even if the Court were to look beyond the text of § 136v(b), petitioners' claims would also be barred under an implied-preemption analysis. The overarching goal of FIFRA's labeling provisions is pesticide labeling that is uniform, understandable, and effective in communicating important information to the public. To implement that objective, EPA has promulgated detailed rules on the optimal font size, color, and positioning of labeling content for pesticides. *See generally* 40 C.F.R. pt. 156. A manufacturer may distribute a pesticide "with the composition, packaging and labeling currently approved by [EPA]." 40 C.F.R. § 152.130(a).[24]

State-law suits requiring changes to the labeling, based on efficacy or any other subject, would "upset this careful regulatory scheme." *United States* v. *Locke*, 529 U.S. 89, 106-107 (2000). If a jury were to sustain petitioners' challenges to the Strongarm label, that would mean that petitioners must change their label—but under federal law, that label may not be changed without EPA permission. 7 U.S.C. § 136a(f)(1); 40 C.F.R. §§ 152.44, 152.46. If a different jury were to reject similar challenges to the same label, however, that result would indicate that there was no basis for EPA to approve any change to the label. Moreover, EPA might well not agree with the judgment that the labeling change effectively required by the adverse jury verdict was appropriate. Manufacturers therefore could quickly find themselves in conflicting positions vis-à-vis both state and federal law. Thus, enforcement of state-law labeling claims would clearly "stan[d] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941).

Moreover, the possibility for application of state common law to labeling is almost endless. State juries might find fault in labels because of perceived insufficiencies in their warnings about efficacy, safety, or method of application. Each jury verdict, to the extent it found fault in a label, would require a different amendment of the label, but such verdicts could well be inconsistent among themselves. For example, one jury might find that warnings about efficacy were insufficiently prominent, but in many cases such warnings could be given greater emphasis only at the comparative expense of warnings about safety. And any compromise in the salience of warnings about safety would presumably be a matter of grave concern to EPA. Such potential variations would not only frustrate Congress's goal of uniformity, but would also deprive EPA of the "the flexibility to choose the appropriate response to evidence of incorrect labeling." 47 Fed. Reg. 40,659, 40,663 (1982).

III. Petitioners May Not Proceed On The Theory That Their State-Law Claims "Parallel" Federal Law

Petitioners argue (Br. 37) that, even if "requirements" in § 136v(b) includes common-law actions, and even if suits challenging efficacy claims are not excluded from that term, their claims nevertheless escape preemption because they

[24] On the question of implied or conflict preemption, we also refer the Court to the brief filed by *amicus* Product Liability Advisory Council.

are based on requirements that are "completely consistent with"—rather than additional to or different from—those required under FIFRA. In particular, petitioners assert (Br. 38) that the state-law duties underlying their claims merely "parallel" FIFRA's prohibition against sale or distribution of pesticides that are "misbranded" because they contain "false or misleading" labeling statements. *See* 7 U.S.C. § 136(q)(1)(A). Petitioners' argument, it bears note, does not depend on any prior determination by EPA that a particular pesticide was "misbranded" (and EPA has made no such determination for Strongarm). To the contrary, petitioners appear to maintain that a state jury may conclude that a pesticide was "misbranded" under federal law (as incorporated into state law) even if EPA would determine (and perhaps already had determined) otherwise.[25]

Whether the issue is viewed as one of express or implied preemption, plaintiffs' purportedly "parallel" claims may not proceed. The regime that petitioners postulate

[25] Petitioners' claims, to be sure, are not *expressly* premised on a violation of FIFRA's provisions or EPA regulations. Rather, they are presented as a violation of state-law duties that in some manner incorporate the federal law of misbranding as an element of the claims—even though Congress rejected any private right of action to enforce FIFRA. But the fact remains that, as petitioners have presented their claims, a jury would have to determine, independently of EPA, that a particular label was "misbranded" under federal law. Such independent determinations would seriously impair the objective of uniformity and centralized administration of labeling requirements reflected in FIFRA. The United States' suggestion in another case that FIFRA "does not bar common law tort claims that are based on a violation of federal regulations—*i.e.*, where federal regulations furnish the standard of care," U.S Amicus Br. 13, *American Cyanamid Co.* v. *Geye*, No. 02-367—is not to the contrary. That statement need not be read as asserting more than, if EPA has previously determined that a pesticide was misbranded, a state-law action based on that determination may lie. Because EPA has made no determination that Strongarm was misbranded, that issue is not presented in this case. *Cf. Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 353-354 (2001) (Stevens, J., concurring in the judgment) (reserving whether state-law fraud-on-FDA claim would lie if FDA had previously concluded that it had been defrauded).

would be utterly inconsistent with the centralized administrative and enforcement mechanism set up by Congress, which intended that the misbranding provisions in FIFRA be enforced exclusively by the federal government.[26] Reflecting that intent, FIFRA's prohibition against misbranding is enforced exclusively by EPA (and, in criminal cases, by the Attorney General), *see* 7 U.S.C. §§ 136g(c)(1), 136k, 136*l*, subject to judicial review in the federal courts alone, *see id.* § 136n.[27] *See also id.* § 136w(a)(1) (EPA authority to prescribe regulations to carry out FIFRA).

Congress rejected a private right of action to enforce FIFRA's labeling requirements precisely because it wanted centralized administrative enforcement of the law. Congress was concerned that private suits to enforce FIFRA's misbranding provisions would "interfere with the orderly administration of the law," disrupting the decisions of the executive branch "by citizens who disagree with the manner in which the President is executing the laws." S. Rep. No. 92-838, pt. II, at 39. In light of that rejection of a private right of action, it is difficult to believe that Congress intended to allow "parallel" private state-law suits that would yield the very same effect as a private right of action to enforce federal law. Petitioners assert (Br. 26), without citing any authority, that the reason for Congress's refusal to enact citizen-suit provisions was its awareness of a pre-existing

[26] *Cf. Buckman*, 531 U.S. at 352 (holding fraud-on-the-FDA claims preempted because "Congress intended that the MDA be enforced exclusively by the Federal Government").

[27] The federal government has extraordinarily broad powers to proceed against a manufacturer of a pesticide that is "misbranded." EPA may forbid the sale or use of any such pesticide, 7 U.S.C. § 136k(a), may proceed in district court to seize or condemn any such pesticide, *id.* § 136k(b)(1), may order its recall, *id.* § 136q(b), may cancel its registration, *id.* §136d(b), and may suspend its registration, *id.* § 136d(c). EPA has elaborate internal hearing and appellate review procedures to determine whether a registrant has violated any provision of FIFRA and, if so, whether any penalties should be imposed or other action should be taken against the registrant or its products. 40 C.F.R. pt. 22.

"background" of private state-law remedies that rendered a federal counterpart unnecessary. As just explained, the legislative record refutes that assertion.[28]

Petitioners' "parallel requirement" theory is premised on the mistaken assumption that the state-law duties underlying their claims are necessarily "consistent with" FIFRA's misbranding prohibition simply because they also target "false or misleading" statements. But the terms "false or misleading" are inherently indeterminate, and their application in specific situations inevitably generates divergent results depending on the decisionmaker and the particular circumstances.[29] That is precisely why, consistent with FIFRA's goal of uniformity in pesticide labeling, EPA has been entrusted with primary authority to interpret those terms. *See* 7 U.S.C. § 136w(a)(1). Because "[t]he judgment as to

[28] Petitioners also suggest (Br. 19)—without citing any authority for the proposition—that state administrative officials may enforce the federal of "misbranding" based on statements in pesticide labels. FIFRA lends no support to this assertion; to the contrary, state administrative enforcement of federal law would also present a threat to the orderly administration of the law desired by Congress. And if state agencies may not enforce federal law, surely private litigants may not, for private enforcement would lead to the "anomalous result" of "grant[ing] greater power" over pesticide labeling "to a single state jury [composed of laypeople] than to state officials acting through state administrative or legislative lawmaking processes." *Medtronic*, 518 U.S. at 504 (Breyer, J.).

[29] Because of the inherent generality of the federal prohibition against "misbranding," this case is quite different from *Medtronic*, where a majority of the Court concluded that a state-law suit could proceed provided that it were squarely based on a violation of a federal requirement under the MDA. *See* 518 U.S. at 494-495 (plurality), 513 (O'Connor, J.). In *Medtronic*, the assumption was that a state-tort suit would allege a violation of a highly specific federal regulation that was "applicable to" the particular device in question. *See id.* at 500-501 (plurality). In such a case, it would presumably be much less difficult to determine whether a medical device complied with the federal rule. In this case, petitioners do not contend that the Strongarm label in any way deviated from the details of any specific EPA regulation about labeling; rather, they argue, at a much more general level, that DAS made statements about Strongarm that were "false and misleading," and so Strongarm was "misbranded." That is exactly the kind of determination for which EPA has sole responsibility.

what constitutes ['false or misleading' labeling] belongs exclusively" to EPA, a "system under which each State could, through its courts, impose . . . its own version of [such] requirements could hardly be more at odds with the uniformity contemplated by Congress." *See Kalo Brick*, 450 U.S. at 325-326 (addressing exclusive agency authority over what constitutes "reasonable" service); *id.* at 331 ("[S]uch a right to sue, with its implied threat of sanctions for failure to comply with what the courts of each State consider reasonable policies, is plainly contrary to the purposes of the Act.").

As this Court has long recognized, uniformity is frustrated even where different decisionmakers apply what is ostensibly the same substantive standard:

> Congress did not merely lay down a substantive rule of law to be enforced by any tribunal competent to apply law generally to the parties. . . . Congress evidently considered that centralized administration of specially designed procedures was necessary to obtain uniform application of its substantive rules and to avoid these diversities and conflicts likely to result from a variety of local procedures and attitudes. . . . A multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law.

Garmon, 359 U.S. at 242-243 (internal quotation marks omitted).[30]

For these reasons, state-law suits that purport to "parallel" FIFRA's misbranding prohibition would seriously im-

[30] Theoretically, a state court entertaining one of petitioners' "parallel" actions could invite EPA to participate as amicus curiae to give the agency's view as to whether a particular pesticide was "misbranded." There is no reason to believe, however, that Congress intended for EPA to become embroiled in private litigation in that fashion (especially given EPA's resource constraints). To the contrary, FIFRA makes clear that determinations as to whether a pesticide is "misbranded" belong before the federal agency.

pair Congress's carefully developed system for federal regulation of pesticide labeling. A key component of that system is the rule that a label, once approved, may not be modified without permission from the EPA. *See* 7 U.S.C. § 136a(f)(1); 40 C.F.R. §§ 152.44, 152.46. Thus, as "different juries in different States reach different decisions" regarding whether a pesticide label is "false or misleading," *cf. Geier*, 529 U.S. at 871, the manufacturer will be obliged to petition EPA to change its label to avoid future liability. EPA could then be presented with the prospect of approving label amendments even if it disagreed with the state courts' application of "false or misleading" that necessitated the change. The existence of such suits would thus subvert the EPA's statutory responsibility, depriving it of the power to develop labeling requirements based on its experience and expertise and instead rendering it accountable to the determinations, based on possibly limited and skewed information, of lay juries.

Petitioners' "parallel requirements" theory posits a federal regulatory scheme that, in the interest of uniformity, entrusts the development of national standards to an expert federal agency but then permits those standards to be formulated on a case-by-case basis by juries in state courts. Quite simply, "[i]t is unlikely—to say the least—that Congress intended to establish such a chaotic regulatory structure." *Ouellette*, 479 U.S. at 491.

IV. All But One Of Petitioners' Claims Concern Labeling And So Are Preempted By FIFRA

Finally, petitioners argue that, even if § 136v(b) does preempt all state-law actions relating to labeling and packaging, at least some of their claims can survive preemption because they do not implicate statements in the labeling for Strongarm. With one minor exception (*see* p. 50, *infra*), both lower courts rejected that contention, which requires close examination of the elements of petitioners' claims under Texas law. This Court need not undertake that interpretive exercise *de novo*, given the Court's "settled and firm policy of deferring to regional courts of appeals in matters that involve the construction of state law."

Bowen v. *Massachusetts*, 487 U.S. 879, 908 (1988). The wisdom of leaving such questions to the court of appeals is particularly clear where, as here, judges of that court have agreed in their interpretation of Texas law. *See* pp. 27-28 n.17, *supra* (citing *Andrus* v. *AgrEvo USA* and *MacDonald* v. *Monsanto Co.*); *cf. McMillan* v. *Monroe County*, 520 U.S. 781, 786 n.3 (1997).

In any event, the premise of petitioners' argument—that applying § 136v(b) to common-law claims would grant pesticide manufacturers blanket immunity from any crop damage that their products might cause—is erroneous. Factually supported manufacturing defect claims—such as a claim that a pesticide was contaminated, or that the manufacturer had negligently affixed the wrong label to the containers of its product, or that the manufacturer negligently deviated from its EPA-accepted confidential statement of formula—should not be preempted.[31] Similarly, some courts have held that FIFRA does not preempt product liability claims based upon a design defect theory.[32]

Preemption, however, does not turn on the name that a claimant has ascribed to his theory of recovery. *See Aetna Health Inc.* v. *Davila*, 124 S. Ct. 2488, 2498 (2004). Whether a design defect theory or any other legal theory is preempted depends upon analysis of several factors, some factual, some legal, and some driven by a claimant's tactical choices. This case is no different. Petitioners' evidentiary

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[31] On the question of claims that, in other cases, would not be preempted by FIFRA, we refer the Court to the *amicus* brief filed by CropLife America and the National Pest Management Association.

[32] *E.g.*, *Arnold* v. *Dow Chem. Co.*, 91 Cal. App. 4th 698 (2001); *Dow Chem. Co.* v. *Ebling*, 723 N.E.2d 881 (Ind. Ct. App. 2000), *aff'd in part, rev'd in part*, 753 N.E.2d 633 (Ind. 2001). The law of design defect liability varies widely among the States. *See generally* Morton F. Daller, *Product Liability Desk Reference, A Fifty-State Compendium* (2004). Because the law of design defect is so jurisdiction-specific and its application so fact-specific, DAS respectfully submits that the Court should avoid any sweeping holding on the relationship between preemptive federal law and disparate state law in this narrow field.

defaults in the district court proved, by process of elimination, that all of their claims are label-based. First, and perhaps most telling, petitioners point to the 2001 supplemental label amendments as the sole piece of liability-creating evidence to support the entirety of their claims.[33] Second, petitioners did not oppose DAS's summary judgment motion with evidence of a safer, feasible alternative design for Strongarm's chemical composition—an essential element of a *prima facie* case under Texas products liability law.[34] Third, petitioners chose not to offer evidence of a manufacturing or formulation defect, a fatal default under Fed. R. Civ. P. 56. Thus, the fact that petitioners' claims are preempted stems from the substance of those claims as well as the evidence that they adduced, and did not adduce, in the district court.

A. Petitioners' Deceptive Trade Practices, Fraud, And Breach Of Warranties Claims Are Preempted

1. Petitioners allege that, in both the Strongarm label and in pre-sale statements made by DAS-authorized sales representatives, DAS represented and warranted that Strongarm was fit as a peanut crop herbicide in West Texas in 2000 when DAS knew that it was not. Pet. App. 16a, 27a-28a; JA 185-190. The Strongarm label on the product purchased by petitioners stated that DAS "warrants that this

[33] The only exceptions are claims by three petitioners who alleged post-application promises of compensation. The district court held that those claims are subject to the label's limitation of remedies. *See* p. 13 n.10, *supra*.

[34] On this point, see the Brief *Amicus Curiae* of the Texas Chemical Council, submitted by William Powers, Jr., Dean of the University of Texas School of Law and principal author of *Cases and Materials in Products Liability* (3d ed. 2002) and *Texas Products Liability Law* (2d ed. 1992). *See also* Tex. Civ. Prac. & Rem. Code § 82.005(a)(1); *American Tobacco Co.* v. *Grinnell*, 951 S.W.2d 420, 437 (Tex. 1997); *Uniroyal Goodrich Tire Co.* v. *Martinez*, 977 S.W.2d 328, 335 n.4 (Tex. 1998); *Smith* v. *Louisville Ladder Co.*, 237 F.3d 515, 521 (5th Cir. 2001). If petitioners had produced evidence of a feasible alternative design that would have prevented the harm they claim to have suffered, summary judgment based upon FIFRA preemption might have been inappropriate.

product . . . is reasonably fit for the purposes *stated on the label*." JA 111 (emphasis added). One of those purposes was use in "all areas where peanuts are grown." JA 108, 175.

The alleged pre-sale, "off-label" statements by DAS representatives about which petitioners complain added nothing to the statements made on the Strongarm label itself.[35] Indeed, both lower courts concluded that petitioners had failed to show that the DAS retailers' comments differed in any material manner from the contents of the Strongarm label. *See* Pet. App. 16a-17a. Petitioners point to nothing in the record that should lead this Court to reverse such a fact-dependent conclusion in which both lower courts have concurred. *Cf. Exxon Co., U.S.A.* v. *Sofec, Inc.*, 517 U.S. 830, 841 (1996).

Because, on the facts of this particular case, there is no basis to distinguish petitioner's off-label claims from their challenges to the label itself, allowing petitioners to recover on their off-label claims would necessarily "induce [DAS] to alter its product label." Pet. App. 15a. If petitioners had adduced evidence sufficient to oppose summary judgment establishing that off-label fraudulent representations had substantially expanded on or departed from the claims on the label, their claims might have survived preemption, but such a case is simply not before this Court.

2. Petitioners attempt to escape preemption of their deceptive trade practices and fraud claims by suggesting (Br. 46) that "the source of the legal duty for fraud has nothing to do with labeling, but rests on a more general obliga-

[35] Petitioners offered three affidavits concerning pre-sale oral representations about Strongarm's fitness for West Texas peanuts. In each case, DAS representatives were alleged to have stated that Strongarm was "excellent" for use on peanuts. JA 147, 152, 157. Under Texas law, such statements about a product's "excellence" are considered nonactionable puffery. *See Barber* v. *Grande Truck Centre, Inc.*, No. 04-00-00802-CV, 2002 WL 31253387, at *3 (Tex. App. Oct. 9, 2002); *Humble Nat'l Bank* v. *DCV, Inc.*, 933 S.W.2d 224, 230-231 (Tex. App. 1996). At most, the comments about Strongarm's "excellence" merely reasserted the statement on the label that Strongarm was fit for use on peanuts.

tion—the duty not to deceive." But preemption under § 136v(b) does not turn on the source of the legal duty; rather, it turns on whether the duty imposes a "requirement[] for labeling" in addition to the federal requirements. A duty to be truthful and nonmisleading in labeling is a "requirement for labeling"—a point reinforced by the fact that federal law itself forbids manufacturers from making false and misleading statements in their labeling.[36] Enforcement of that duty would certainly affect the pesticide's labeling; if a state jury found that Strongarm's labeling was false and misleading, then DAS would have to change it.

Second, with respect to their breach of express warranties claims, petitioners contend (Br. 43-44) that warranties are purely contractual arrangements between private parties, and so actions for breach of warranty are not "requirements" imposed by the State. Even if *some* kinds of express warranties might be properly understood merely as "contractual commitment[s] voluntarily undertaken," *Cipollone*, 505 U.S. at 525 (plurality), the warranties at issue here cannot be placed in that group. Far from being voluntarily undertaken commitments, DAS's statements about proper crop use were "mandated disclosure[s] . . . specifically required by federal law and approved by the EPA." *Welchert* v. *American Cyanamid, Inc.*, 59 F.3d 69, 72-73 (8th Cir. 1993). Both the statute and EPA's implementing regulations required DAS to include a statement about Strongarm's proper uses in the labeling. *See* 7 U.S.C. § 136(q)(1)(F) (pesticide is misbranded if labeling does not contain directions for use); 40 C.F.R. § 156.10(i)(2)(iii) (label must include directions for use, including "the site(s) of application, as for example the crops . . . to be treated"). To permit breach of warranty claims based on representations required by FIFRA and EPA regulations would "allow state courts to sit, in effect, as super-EPA review boards that

[36] *Cf. Jones* v. *Rath Packing Co.*, 430 U.S. 519, 532 (1977) (statutory provision "governing the accuracy of" statements made on a label is a "labeling requirement[]").

could question the adequacy of the EPA's determination of whether a pesticide registrant successfully complied with the specific labeling requirements of its own regulations." *Welchert*, 59 F.3d at 73.

B. Petitioners' Negligent Testing Claim Is Preempted

Petitioners seek damages for DAS's alleged negligence in developing, testing, and manufacturing Strongarm. The courts below correctly held that, as a matter of Texas law, this claim is really a "variation of an action for failure to warn" (Pet. App. 19a; *see id.* at 30a) and so is preempted. The gravamen of petitioners' negligence claim is not that the Strongarm they used was not properly manufactured or tested; petitioners do not suggest, for example, that the Strongarm they purchased was contaminated in the manufacturing process, or that Strongarm is inefficacious in every application and that DAS would have discovered that defect had it tested the product properly. Rather, petitioners assert that DAS failed to alert them to the fact that Strongarm was likely to be harmful to peanut crops in soils with pH above 7.2. Moreover, the central piece of evidence on which petitioners rely to advance that argument is the fact that DAS petitioned EPA for a change in its label in 2001 to advise against use in elevated-pH soils, after DAS received complaints about Strongarm. *See* p. 12 n.9, *supra*. Because their negligence claim would require a showing that Strongarm's labeling "should have included additional, or more clearly stated, warnings," that claim rests squarely on a failure-to-warn theory and is preempted. *Cf. Cipollone*, 505 U.S. at 524 (plurality).

Petitioners suggest (Br. 47-48) that a negligent development, testing, and manufacturing claim *might* be unrelated to labeling and so should avoid preemption. This might well be true in another context, such as where a plaintiff could show that the product was contaminated during production or that the manufacturer had departed from the EPA-approved composition in the production process. *See, e.g., In re Dupont-Benlate Litig.*, 859 F. Supp. 619, 623

(D.P.R. 1994). That point, however, says nothing about whether *petitioners'* negligence claim is related to labeling. Both courts below found that it was (*see* Pet. App. 19a, 30a). and petitioners point to nothing in the record or the case law that calls that conclusion into question.[37]

Second, petitioners argue (Br. 48) that success on their claim would have the effect of restricting Strongarm's use in West Texas, and that "because § 136v(a) empowers States directly to restrict pesticide sale or use, a damages suit that indirectly does so should not be preempted even if it might induce a label alteration." This argument runs directly counter to FIFRA's text and structure. FIFRA does not treat the power to affect a pesticide's label as a lesser-included aspect of the power to regulate the use or sale of a pesticide. Quite the reverse; § 136v, read as a whole, makes clear that, while States may adopt various means to restrict pesticide use (§ 136v(a)), they may not achieve their regulatory goals by forcing manufacturers to alter their labels (§ 136v(b)). Prohibiting or restricting use of a particular pesticide within the boundaries of a State can be characterized as an exercise of the State's police power to protect its citizens, but allowing a State to affect a pesticide's label can have broad implications for distribution of a pesticide in interstate commerce—a matter over which Congress has long exercised regulatory authority.

C. Petitioners' Strict Liability Claim Is Preempted

Petitioners claim that DAS should be held strictly liable for a design or manufacturing defect that rendered Stron-

[37] Petitioners erroneously describe *Quest Chemical Corp.* v. *Elam*, 898 S.W.2d 819, 820-821 (Tex. 1995) (per curiam), as standing for the proposition that negligent testing, manufacturing, and formulating claims should escape preemption. *See* Pet. Br. 47. In fact, Quest held that (as in this case), "[a]lthough causes of action for negligent testing, manufacturing, and formulating might escape FIFRA preemption, the statute preempts [plaintiff's] particular strict liability and breach of implied warranty claims because they are based solely upon Quest's failure to provide adequate warnings and instructions on its product." 898 S.W.2d at 820-821.

garm "unreasonably dangerous as a herbicide." JA 189. The court of appeals acknowledged that some defective-design claims might survive FIFRA preemption, but found petitioners' claim to be preempted because it is "merely a disguised claim for failure to warn." Pet. App. 18a. As the court of appeals explained, petitioners "did not claim that Strongarm is unreasonably dangerous for use on all peanut crops; rather, they asserted that Strongarm is dangerous when applied to crops in soil with high pH levels." *Id.* Thus, "the heart of [petitioners'] grievance" is that "Strongarm is dangerous to peanut crops in soils with a pH level over 7.0, and that was not disclosed to them." *Id.* Because petitioners' design defect claim is fundamentally a failure-to-warn claim, "[i]t is inescapable that success on this claim would . . . necessarily induce [DAS] to alter the Strongarm label," and the claim is therefore preempted. *Id.* at 19a.

Petitioners attack this holding on grounds similar to those they raise against the court of appeals' conclusion that their negligence claim was preempted. They contend (Br. 40) that inaccurate labeling or promotion is not a necessary element of a strict liability design defect claim under Texas law. The court of appeals recognized as much. *See* Pet. App. 18a. Other courts have also recognized that strict liability defective design or manufacturing claims may fall outside FIFRA's preemptive reach. *See, e.g., Reutzel* v. *Spartan Chem. Co.*, 903 F. Supp. 1272, 1281-1282 (N.D. Iowa 1995). But, as with their negligence claim, this theoretical point says nothing about whether *petitioners'* strict liability claim is preempted. That claim turns on the allegation that Strongarm is not safe for use in high pH soils and that the Strongarm label is thus inaccurate—not that Strongarm is unreasonably dangerous in all its applications. "If a state law claim is *premised* on inadequate labeling," as petitioners' is, "the impact of allowing the claim would be to impose an additional or different requirement for the label." *National Bank of Commerce* v. *Dow Chem. Co.*, 165 F.3d 602, 608 (8th Cir. 1999).

D. Petitioners' Claim Based On Post-Sale Representations Is Not Before This Court

Finally, petitioners seek to advance a claim for fraud based on DAS's failure to abide by post-sale promises that its representatives allegedly made to growers, offering to compensate them for crop losses caused by the pesticide. *See* JA 190-191. The district court ruled that those claims are not preempted because they are not predicated on the Strongarm label, but that they are barred under state law by the limitation-of-remedies provision on the Strongarm label. *See* Pet. App. 28a-30a. Contrary to their representation to this Court (Br. 49 & n.35), petitioners did not challenge the district court's limitation-of-remedies ruling in the court of appeals, *see* Pet. C.A. Br. 51-55,[38] and the court of appeals did not address it. Thus, those claims, dismissed on a state-law ground by the district court and not passed upon by the court of appeals, are not properly before this Court. *See Youakim* v. *Miller*, 425 U.S. 231, 234 (1976).

CONCLUSION

The judgment of the court of appeals should be affirmed.

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[38] Petitioners' brief below offered only one sentence of argument about the claim based on the post-sale statements (what petitioners called their "reimbursement" claims): "The district court was correct in finding that the reimbursement representation was off-label and thus not preempted." Pet. C.A. Br. 52. That sentence raises no challenge to the district court's holding that the post-sale claim *was* barred by the limitation-of-remedies provision on the Strongarm label. The remainder of the discussion in petitioners' brief below concerned the pre-sale claims alone.

(26)

No. 03-388

IN THE

Supreme Court of the United States

DENNIS BATES, ET AL.,
Petitioners,
v.

DOW AGROSCIENCES LLC,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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STATEMENT PURSUANT TO RULE 29.6

Petitioners' 29.6 Statement was set forth at page iii of petitioners' opening brief, and there are no amendments to that Statement.

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For more than a century until the mid-1990s, courts routinely recognized the rights of farmers to bring state-law claims for crop damage caused by unsafe pesticides, either because the product itself was defectively designed or manufactured, or because its label's use instructions were inadequate. Congress did not intend to affect those pre-existing remedies in the 1972 FIFRA amendments. Instead, it expressly retained a robust role for States to regulate the "sale or use" of pesticides, § 136v(a), and to approve new uses for special local needs, § 136v(c). The scope of preemption in § 136v(b) must be read in light of Congress's preservation of this critical and expansive state regulatory role.

The farmers who are petitioners here suffered substantial crop damage in the fields where they used Dow's Strongarm product; indeed, some petitioners did not use Strongarm in certain of their fields, where they experienced record crop production. Unlike other farmers who were prepared to accept pennies on the dollar in mediation for Dow's broken promises to remedy harms it had caused, petitioners had every right to bring state damages claims for fraud, strict liability, negligence, and breach of warranty. The Fifth Circuit erroneously held all of those claims preempted even though they (1) are based on the inefficacy of Strongarm – which EPA concededly does not review when registering a pesticide; (2) are based on state requirements that simply parallel FIFRA's misbranding requirements; and (3) do not impose labeling requirements different from or in addition to those imposed by FIFRA.

Even assuming FIFRA preempts claims challenging the label's use instructions, however, the Fifth Circuit erred, for example, in dismissing the farmers' defective design and manufacturing claims inasmuch as they challenge the safety of the Strongarm product itself (even apart from its false and misleading label), and the claims based on post-sale, off-label misrepresentations. Dow concedes that defective design, manufacturing, testing, and post-sale claims are generally not preempted. Those concessions compel remand. Dow nonetheless would give § 136v(b) such a broad scope as to denude

§ 136v(a) of practical effect: any time a manufacturer is "induced" to change the label in response to liability, damages remedies would be preempted. In *Medtronic* and *Cipollone*, this Court rejected similarly overbroad interpretations of preemption provisions that were broader in scope than § 136v(b) and did not expressly authorize States to regulate "sale or use" of products. As in *Medtronic*, which this Court also reviewed on the pleadings, the Court should reject Dow's preemption theories and remand for factual development and trial.

I. STATE-LAW DAMAGES CLAIMS ARE NOT PREEMPTED BY FIFRA

Congress did not intend for § 136v(b) to be an all-encompassing preemption provision. Dow focuses myopically on the word "requirements" in § 136v(b), but largely ignores the multiple ways in which § 136v(a) and (c) expressly permit States to regulate pesticides in ways that directly and indirectly induce a manufacturer to change its EPA-approved label. Dow thus disregards the fundamental principle that "[s]tatutory construction is a holistic endeavor." *Koons Buick Pontiac GMC, Inc. v. Nigh*, 125 S. Ct. 460, 466 (2004) (internal quotation marks omitted).

A. Section 136v(b) Evinces No Intent To Preempt Damages Claims Inducing A Label Change

The most logical way to read § 136v(b), in light of the text, structure, and history of the provision, is that Congress intended to preempt only state positive-law requirements that directly force a manufacturer to change a label. That construction is the most consistent with the long history of farmers bringing claims against manufacturers for damage and the absence of any indication that Congress intended to affect those remedies.

In *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 614 (1991), this Court explained that FIFRA did not occupy the field of pesticide regulation and that FIFRA must be interpreted in light of the presumption *against* preemption: the "specific grant of authority in § 136v(a) consequently does not serve to hand back to the States powers that the statute

had impliedly usurped. Rather, it acts to ensure that the States could continue to regulate use and sales even where, such as with regard to the *banning of mislabeled products, a narrow pre-emptive overlap might occur.*" *Id.* (emphasis added). Accordingly, the labeling uniformity sought in § 136v(b) is profoundly tempered by a State's express authority in § 136v(a) and (c) to regulate pesticide sale or use within its borders and to impose locality-specific requirements. That authority is not preempted even when it might induce a label change, because EPA has the final say on labeling, thereby ensuring uniformity.

Indeed, EPA regulations permit States to require that a pesticide be distributed with a supplemental label stating its "restricted use" within the State, so that state sale and use regulations are not undermined by lack of notice to consumers. *See* 40 C.F.R. § 162.153(e)(5) (States have authority directly to "require supplemental labeling for the product or use containing additional appropriate precautions, and a statement that the product or use is for restricted use within that State," even though FIFRA would not require the pesticide to be labeled for restricted use). That is not materially different from what Dow was supposedly "induced" to do by the farmers' reports of Strongarm's inefficacy: add a supplemental label for distribution only in Texas and two adjoining States providing (among other things) that Strongarm should not be used in soils of 7.2 pH or greater. Given the substantial authority for States to regulate pesticides – the result of which may be directly to require a manufacturer to change its label – damages claims based on use of a product that might *indirectly* induce a manufacturer's voluntary label change are not preempted.

Although the preemption provision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), is quite similar to the wording of § 136v(b) here – and five Justices held that *none* of the Lohrs' claims was preempted – the case for non-preemption is even stronger here. The Medical Device Amendments ("MDA") did not contain an express provision conferring broad authority on States to regulate the "sale or use" of medical devices. Rather, the Food and Drug Administration ("FDA") had regulatory authority to determine when certain more stringent state rules would not be preempted. In § 136v(a), however, *Congress* concluded that States themselves have broad authority to regulate pesticides more stringently than federal law in ways that invariably will directly and indirectly affect labels, and a State need not first get EPA's permission to do so. It is therefore inconsistent with FIFRA's statutory structure to read the word "requirements" in § 136v(b) as a sweeping prohibition on common-law claims; *Medtronic*'s majority view that under the MDA "requirements" includes damages claims does not control here.

B. Dow's Reliance On Legislative History Is Misplaced

Nothing in the legislative history suggests any intent to preempt damage actions. Indeed, it confirms that § 136v(b) is addressed almost exclusively to the authority of state legislatures and pesticide agencies, not to the availability of state-law remedies. *See* U.S. Amicus Br. at 18-31, *Etcheverry v. Tri-Ag Serv., Inc.*, No. S072524 (Cal. filed Mar. 23, 1999).[1] The absence of any discussion of eliminating state damages remedies stands in sharp contrast to the voluminous testimony on the harms caused by pesticides and debates over how far States should be permitted directly to regulate the pesticide industry. *See id.*; Pet. Br. 26; Peanut Growers Br. 19 & n.38, 20-30. No industry witness or other party expressed any concern that damages actions created uniformity problems, but they did complain about the types of state labeling requirements – formatting, coloring, wording – that had sometimes precluded a national label. *Id.* at 24-25. That history confirms that § 136v does not speak to common-law damages actions, but only state positive law.[2]

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[1] To the extent the legislative history refers to tort liability at all (and it does so only briefly), witnesses and members of Congress assumed it would remain unaffected by the 1972 FIFRA amendments. *See* Western Peanut Growers Ass'n et al. *Amicus* Br. 14-15 & nn.30-31.

[2] Dow relies (at 29 & n.19) on two references in the House report to state labeling being "completely preempted," H.R. Rep. No. 92-511, at 1-2, 16 (1971), but those references are inconsistent with the broad non-

Dow repeatedly (at 4, 29-30, 39-40) invokes Congress's rejection of a "citizen suit" provision, but history here validates the farmers' position. Senate Commerce Committee amendments proposed a "citizen suit" provision that explicitly left undisturbed pre-existing common-law remedies. The proposal permitted only "injunctive relief" against the EPA Administrator for failure "to perform an act or duty under this Act which is not discretionary" and against any "person" (including the United States or a State) "alleged to be in violation of" certain requirements in the Act. S. Rep. No. 92-970, at 4 (1972). The plain intent of the proposal, therefore, was to empower private attorneys general to ensure that FIFRA was enforced; it was not geared in any way to the kinds of private damages remedies for persons harmed by pesticides. To avoid any ambiguity about including a provision for injunctive relief without a corresponding damages remedy, however, the proposal expressly saved common-law damages actions: "Nothing in this section shall restrict any right which any person (or class of persons) may have under any other statute *or under common law* to seek enforcement of any regulation or order *or to seek any other relief.*" *Id.* at 5 (emphases added).

Congress received criticism of that proposal, not because it explicitly saved common-law suits from preemption, but because it authorized suits against the government for failure to act. Accordingly, the Senate Agriculture Committee proposed an amendment to remove authorization for citizen suits against the EPA Administrator. *See* S. Rep. No. 92-838, Pt. II, at 40 (1972). Importantly, and contrary to Dow's misleading description, the Agriculture Committee obviously perceived that a savings clause was otherwise unnecessary – because no other provision of FIFRA preempted state-law

preemption provisions of § 136v(a) and (c) that Congress ultimately adopted. The House report commented on a bill that conferred limited authority on States to regulate only one class of pesticides, those that FIFRA required to be designated for restricted use. As enacted, however, § 136v went much farther. *See* Peanut Growers Br. 26-28 (floor debates addressed concern that bill would gut state use laws stricter than FIFRA).

claims. Rather, its objection to the Commerce Committee proposal was that "courts should not be further burdened with suits by citizens who disagree with the manner in which the President is executing the laws." *Id.* at 39. When the Conference Committee deleted that provision in its entirety, its cursory explanation was that it had "deleted" a provision conferring "[a]uthority for certain types of citizen suits against the Administrator." H.R. Conf. Rep. No. 92-1540, at 34 (1972). There was no mention of any intent to affect common-law remedies. Without the citizen suit provision, those remedies were not otherwise perceived to be threatened by FIFRA. Seen in its proper light, this proposal supports the conclusion that Congress had no intent to preempt damages remedies.[3]

II. PETITIONERS' CLAIMS ARE OUTSIDE THE SCOPE OF § 136v(b) PREEMPTION

A. Efficacy Claims Are Not Preempted

Both parties and the government now agree that "EPA does not routinely scrutinize product efficacy in the initial registration process." Dow Br. 8; Gov't Br. 21 ("EPA has generally waived such requirements and typically does not conduct independent product efficacy evaluations.") (citing PR 96-4 (JA 228-35)). Dow and the government also concede that EPA did *not* base its conditional registration of Strongarm on any assessment of whether Strongarm harms peanut crops. Indeed, while Dow asserted in its opposition to certiorari that EPA in fact had assessed target-crop phytotoxicity, its merits brief is now silent on that issue. *See* Pet. Br. 33-35 & n.23 (rebutting those claims). Although Dow contends (at 10) that it submitted efficacy data that "reflect[] . . . target-crop phytotoxicity," it does not claim EPA reviewed them in registering

[3] Dow misconstrues commentary that the citizen-suit provision would "interfere with the orderly administration of the law" by omitting the preceding part of the quoted sentence, which addresses this concern to "professional litigants," and not persons injured by pesticides. S. Rep. No. 92-838, Pt. II, at 39 (criticizing that "costs of litigation [would] be awarded to any party whenever the court deemed appropriate without regard to whether such party prevailed in the suit").

Strongarm, and Dow does not even mention those data in its legal arguments as a basis for preemption.[4]

Notwithstanding EPA's non-consideration of efficacy, Dow claims (at 32-33) that § 136v(b) preemption is based only on requirements imposed by "FIFRA itself" and is unaffected by whether EPA assesses efficacy claims before granting a pesticide registration. In 1978, however, Congress amended "FIFRA itself" to *remove* the requirement that a pesticide's efficacy claims pass EPA muster as a precondition to registration. *See* Pet. Br. 7 (discussing § 136a(c)(5)). In any case, the phrase "under this subchapter" in § 136v(b) can, as even Dow recognizes (at 35), easily be "construed as referring to both FIFRA and its implementing regulations." *See* § 136w(a)(1) (EPA "may prescribe regulations to carry out the provisions of this subchapter"). The government also concedes as much.[5] Thus, FIFRA's removal of an efficacy review requirement, coupled with EPA's waiver, means that common-law claims challenging a pesticide's efficacy do not impose labeling "requirements" within § 136v(b)'s preemptive ambit. Such claims likewise raise no implied preemption concerns by posing an obstacle to accomplishment of Congress's aim of removing the burden on EPA to examine efficacy claims prior to registering a pesticide.

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[4] To the extent Dow suggests it can control the scope of preemption by submitting un-required data that EPA does not review, that suggestion should be rejected out of hand. In any case, a data submission requirement cannot be viewed as preemptive under FIFRA. The States necessarily have authority to require data submissions to fulfill their role in regulating pesticides under § 136v. *See, e.g.*, § 136a(c)(5) (last sentence) ("If a pesticide is found to be efficacious by any State under section 136v(c) of this title, a presumption is established that [EPA] shall waive data requirements pertaining to efficacy for use of the pesticide in such State."); § 136w-1 ("For the purposes of this subchapter, a State shall have primary enforcement responsibility for pesticide use violations").

[5] *See* Gov't Br. 4-5 ("Section 136v(a) recognizes that, as a general matter, States retain their historic authority to regulate pesticide sale or use, provided that a State does not permit a sale or use that FIFRA, *or EPA's implementing regulations*, prohibit") (emphasis added).

Moreover, EPA's authority to take corrective action *after* a pesticide has caused harm is no substitute for its failure to require accurate efficacy claims as a prerequisite to a pesticide's entry into the marketplace. *Medtronic* makes clear that an agency's statutorily authorized decision not to assess a product's efficacy before permitting it on the market means a state damages action is not in addition to or different from any relevant federal efficacy requirement. *See* Pet. Br. 33, 36. In *Medtronic*, FDA did not require the pacemaker it approved to take any particular form with respect to efficacy and safety, only that it be substantially equivalent to the design of a device already on the market. *See* 518 U.S. at 493-94. That process, like the EPA's here, "provide[d] little protection to the public" because the pacemaker was never "formally reviewed under the [MDA] for safety or efficacy." *Id.* at 493 (internal quotation marks omitted). This Court unanimously deemed irrelevant to preemption that the pacemaker (like Strongarm) had a continuing duty to satisfy statutory misbranding requirements. *Id.*

Dow attempts (at 33-34) to distinguish *Medtronic* on the erroneous ground that preemption rested on whether the agency itself had promulgated a preemptive requirement. But Dow overstates the proposition, for the Court said only that preemption would occur as a result of an agency-promulgated requirement "in most cases" – not all cases. 518 U.S. at 496. Indeed, the Court's analysis of the substantial-equivalence process (which Dow's argument ignores) focused not on whether the *agency* had acted to impose a requirement, but rather on the substantial-equivalence process and standards in the *statute* enacted by Congress. *See id.* at 492-93. And the Court specifically rejected the argument that FDA's action approving the pacemaker, along with the agency's continuing authority "to exclude the device from the market if its design is changed," constituted a preemptive requirement. *Id.* at 492. Similarly, here EPA approved Strongarm with no "requirement" (statutory or otherwise) that its efficacy claims be accurate as a precondition of registration.

Dow's reliance (at 34-35) on Congress's failure in 1978 substantively to amend § 136v(b) while inserting a technical change to that provision is similarly misplaced. Once Congress removed the "requirement" that a pesticide be shown to be efficacious before it can be marketed, there was no longer any basis (assuming there ever had been) in finding efficacy as a preemptive requirement "under this subchapter." § 136v(b). Nor can anything be read into congressional inaction after certain lower court decisions in the mid-1990s found preemption after *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). First, EPA's PR 96-4 explained that those courts had wrongly assumed that EPA actually reviewed efficacy claims as a prerequisite to registration; thus, Congress's inaction reflects agreement with PR 96-4. *See* Pet. Br. 32 & n.21. In any case, the congressional inaction "argument deserves little weight in the interpretive process," especially "when, as here, Congress has not comprehensively revised a statutory scheme but has made only isolated amendments." *Alexander v. Sandoval*, 532 U.S. 275, 292 (2001) (alterations and internal quotation marks omitted).[6]

Finally, there is no merit to Dow's claim (at 35-36) that, in light of EPA's efficacy waiver, a damages suit would impose a state requirement "in addition to" a federal requirement. States plainly are permitted to make efficacy determinations in deciding whether to ban or restrict the sale or use of a pesticide under § 136v(a), and those evaluations may involve analysis of pesticide label claims and an assessment that they are false and thus misbranded. *See Mortier*, 501 U.S. at 614. Under Dow's reading of "in addition to," such state actions would be preempted, a result plainly inconsistent with congressional intent. In *Medtronic*, this Court rejected the very same argument made by the manufacturer. *See supra* p. 8; Pet. Medtronic Br. at 44-46, Nos. 95-754 & 95-886 (U.S. filed Mar. 1, 1996). Indeed, Congress explained the efficacy waiver precisely in terms that allowed EPA to consider the effect of market forces and private lawsuits in policing industry's sale of ineffective products. *See* Pet. Br. 31.

[6] Moreover, EPA expressly based its efficacy waiver on the availability of damages suits to remedy those harmed by ineffective pesticides. *See* Pet. Br. 31. Although the government argues (at 23 n.11) that EPA's statement is consistent with some claims not being label-related, such as design or manufacturing defect claims, EPA was addressing only the failure-to-warn claims that all three of the cases cited in PR 96-4 found preempted. *See* JA 231-32. In addition, although the government claims (at 20) that it reexamined its position on these issues after the California Supreme Court issued its ruling in *Etcheverry*, it does not dispute that that court based its decision on the erroneous assumption that EPA's efficacy waiver did *not* include target-crop phytotoxicity. *See* Pet. Br. 32 n.20; *cf.* Gov't Br. 4, 21 (agreeing that EPA's efficacy waiver *does* include target-crop phytotoxicity). The government therefore offers no principled basis for its preemption flip-flop.

B. The Farmers' Claims Are Consistent With FIFRA's Misbranding Requirements

Because the farmers' claims can be tried to a jury in a manner consistent with FIFRA's misbranding prohibition, they do not impose any "requirements for labeling or packaging in addition to or different from those required under [FIFRA]." § 136v(b). All nine Justices in *Medtronic* reached the same result under the similarly worded preemption clause in the MDA. *See* Pet. Br. 37-39. The Court found a remand for trial appropriate where (as here) the "precise contours of [plaintiffs'] theory of recovery have not yet been defined" because the "pre-emption issue was decided on the basis of the pleadings." 518 U.S. at 495.

1. *Medtronic*'s unanimous holding that parallel state requirements are not preempted is controlling here. Dow acknowledges (at 40 n.29) *Medtronic*'s conclusion "that a state-law suit could proceed provided that it were squarely based on a violation of a federal requirement under the MDA." It claims (*id.*), however, that "the assumption was that a state-tort suit would allege a violation of a highly specific federal regulation that was applicable to the particular device in question" and would therefore not be preempted; whereas a state requirement parallel to a "general" federal requirement would be preempted. There is no support for Dow's reading. The Court characterized the federal requirements that would not preempt parallel state law as "*general* rules regulating manu-

facturing practices and labeling." 518 U.S. at 492 (emphasis added). The misbranding provision here likewise provides generally that the product is misbranded if it does not "contain directions for use which are necessary for effecting the purpose for which the product is intended." § 136(q)(1)(F). As the Solicitor General told the Court in *Medtronic*, state juries could be instructed "consistent with the federal labeling requirements" to determine whether the label was "false or misleading" or contains "adequate directions for use." U.S. Amicus Br. at 27-28, Nos. 95-754 & 95-886 (U.S. filed Mar. 13, 1996).[7] FIFRA compels the same result.

Although the government now supports preemption of parallel state requirements under FIFRA, it erroneously contends (at 26 n.13) that *Medtronic* based its parallel-requirements holding on the ground that state requirements in conflict with a device-specific federal requirement are preempted. But the *Medtronic* majority rooted its holding on the fact that parallel state "damages remed[ies] were not 'different from, or in addition to,'" federal requirements. 518 U.S. at 495 (quoting 21 U.S.C. § 360k(a)(1)). To be sure, as the government notes, the Court added that its textual analysis was informed by FDA regulations, but the cited regulations provided that *even a device-specific FDA regulation* "'does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.'" *Id.* at 496-97 (quoting 21 C.F.R. § 808.1(d)(2) (1995)). Thus, a parallel

[7] Dow (at 42) and the government (at 25) rely on a discussion in *Geier v. American Honda Motor Co.*, 529 U.S. 861, 871 (2000), of the possibility that juries can "reach different decisions on similar facts." There, however, the Court addressed a preemption provision prohibiting state requirements that are not "identical to" federal ones, which is quite unlike the preemption provision at issue here (and in *Medtronic*). *Id.* at 867. As Justice Breyer's opinion for the Court explained, that language meant preemption even of state standards "that might stand in harmony with federal law." *Id.* at 871; *see id.* at 868 (explaining that preemption would attach to "nonidentical state standards . . . even if the federal standard merely established a minimum standard").

state-law misbranding claim escaped preemption only because it was not "different from, or in addition to," federal law.

Dow's implausible argument against parallel state-law requirements is rooted in its contention that FIFRA makes EPA the sole decisionmaker on whether a pesticide is misbranded. That claim lacks any textual grounding in § 136v(b)'s preemption language or § 136(q)'s misbranding requirements. Indeed, all nine Justices in *Medtronic* rejected an indistinguishable claim without discussion, because the medical device manufacturer had (like Dow here) argued at some length against parallel state-law requirements by claiming that "[t]he inability of courts to ensure consistency in practice would create an irregular pattern of liability exposure for device manufacturers, undermining the congressional intent to impose uniform requirements." Cross-Respondent Medtronic Br. at 44, Nos. 95-754 & 95-886 (U.S. filed Mar. 29, 1996); *see id.* at 44-46.[8]

Dow cites (at 38-39) FIFRA's enforcement provisions as support for a supposedly exclusive role by EPA, but FDA also had similar enforcement authority under the MDA. That fact was not taken to preempt parallel state laws, as the Court subsequently reaffirmed in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 353 (2001) ("*Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements"). Dow's reliance (at 38-39) on *Buckman* is inapposite, for the claim held preempted there was for fraud on the agency alleging that the "but-for" cause of plaintiff's injuries was fraudulent representations made to FDA, without which the medical device would not have been allowed on the market. Here, however, the farmers' claims are based on fraudulent statements made directly to them by

[8] Notably, the decision unanimously reversed on this point in *Medtronic* had relied on a FIFRA case holding that allowing a lay jury to pass on negligence and failure-to-warn claims that paralleled FIFRA's labeling standards would usurp EPA's role. *See Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1343 (11th Cir. 1995) (citing *Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir. 1993)).

the manufacturer, as well as design and manufacturing defects. *See* 531 U.S. at 352 ("[I]t is clear that the *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements.").

2. Dow's theory of uniformity also contravenes the text and structure of FIFRA, which gives substantial power to the States to interpret and enforce its provisions. *See Mortier*, 501 U.S. at 615; § 136t(b). Adoption of Dow's theory would require the incongruous conclusion that § 136v(b) preempts Texas's pesticide agency from restricting the use of Strongarm where soil pH was 7.2 or greater, because that would conflict with the original label's claims that it was appropriate for use in all areas where peanuts are grown. Indeed, under § 136v(a), a State may apply a more stringent misbranding standard under state law and ban a pesticide that is not mislabeled under FIFRA. It follows *a fortiori* that a state standard that is parallel to federal requirements cannot be preempted.[9] Thus, a jury applying standards of state law parallel to FIFRA's misbranding requirements would not impose any requirement that § 136v(b) preempts.

In addition, § 136v(c) allows a State to register pesticides "for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of [FIFRA]." § 136v(c)(1). EPA requires a State registering a new product to require that its "labeling meet[] all applicable criteria of [40 C.F.R.] § 156.10." 40 C.F.R. § 162.153(e)(2). Rule 156.10, in turn, proscribes "false or misleading statement[s]," including those concerning "the effectiveness of the . . . pesticide."

[9] State misbranding statutes are often premised on FIFRA. *See, e.g.*, Tex. Agric. Code Ann. § 76.023 ("pesticide or device is misbranded if: (1) it is subject to registration under FIFRA and it does not fully comply with the labeling requirements of [EPA]"); N.Y. Envtl. Conserv. Law § 33-0101(32)(i) (pesticide is misbranded if its labeling "fails to conform to the labeling requirements of [FIFRA]"). *Cf.* EPA, FIFRA Statute, Regulations & Enforcement ("State laws generally mirror FIFRA."), *at* http://www.epa.gov/compliance/civil/programs/fifra/fifraenfstatreq.html.

Id. § 156.10(a)(5)(ii); *see also id.* § 156.10(*i*)(1)(i) ("directions [for use] must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment"). A State therefore is *required* in registering a pesticide for a state-specific use to mandate labeling in compliance with FIFRA – including FIFRA's own misbranding requirements. Dow thus cannot be correct that a court is precluded from interpreting those very same requirements, much less lack the power to apply a parallel state-law standard to judging remedial claims.[10] Dow's contention that FIFRA requires all misbranding determinations to be made by EPA cannot withstand scrutiny, and Dow fails to explain why having the same standard decided in the context of a private lawsuit would impose a requirement "in addition to or different from" parallel FIFRA misbranding requirements. *Cf. California v. Zook*, 336 U.S. 725, 736 (1949) (no preemption where the "case concerns only the state's mechanisms for enforcing a statute identical with that of the federal government").[11]

[10] *See also* § 136g(a)(1)-(2) (empowering "any State duly designated by [EPA]" to inspect samples of any pesticides and "containers or labeling for such pesticides," so long as the State "include[es] a statement as to whether a violation of the law is suspected").

[11] Dow's reliance (at 41) on *San Diego Building Trades Council v. Garmon*, 359 U.S. 236 (1959), is misplaced. That case concerned an area of labor law (union picketing) in which the Court found Congress to have established federal preemption through the exclusive authority vested in the National Labor Relations Board. *See Brown v. Hotel & Rest. Employees*, 468 U.S. 491, 502 (1984); *see also English v. General Elec. Co.*, 496 U.S. 72, 86-87 n.8 (1990). In *Mortier*, however, this Court expressly rejected that same approach to FIFRA. *See* 501 U.S. at 605-07; Pet. Br. 21. In view of the substantial authority in § 136v for States to regulate mislabeled products, no such implied preemption (much less a presumption of it) could be applicable here. *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 321 (1981), rested on the ground that pervasive federal regulation giving the Interstate Commerce Commission "exclusive and plenary" jurisdiction to regulate rail-service abandonments was "critical to the congressional scheme," but here, again, FIFRA expressly preserves substantial state authority to ban

C. The Farmers' Claims Do Not Add "Different" or "Additional" Requirements Under § 136v(b)

Even if this Court rejects the foregoing arguments on efficacy and misbranding, it must still reverse because the claims asserted by the farmers would not impose requirements "different from or in addition to" FIFRA requirements. Importantly, this case was dismissed before discovery had occurred and the farmers' claims could be fleshed out with evidence on the feasibility of alternate, safer formulations of Dow's product that would not burn peanut roots in high pH soils. Accordingly, the evidence after discovery and trial need not be based on a failure-to-warn theory. Following *Cipollone*, *Medtronic* re-emphasized that the relevant "requirements" for preemption were the legal duties underlying each state-law claim. *See* Pet. Br. 40-48. Because the legal duties flowing from the farmers' claims would not impose "labeling requirements," their claims are not preempted.[12] Dow repeat-

mislabeled products, which necessarily entails the authority to interpret federal misbranding standards.

[12] Notably, the government takes no position on whether the farmers' individual claims survive preemption. Instead, it claims the farmers "did not challenge the court of appeals' ruling that petitioners' claims are 'label-related' in the sense that 'a judgement [*sic*] against [Dow] would induce it to alter its product label.'" Gov't Br. 27 (quoting Pet. App. 15a). The government's plea, which seeks to dodge its contradictory positions taken just five years ago, simply ignores the question on which certiorari was granted: "Which, if any, state-law crop damage claims are preempted by [FIFRA]." Pet. i. It also overlooks the statement (Pet. 28) that this case "includes the vast array of claims that would normally be brought in a crop injury case: breach of warranty, fraud, violations of state consumer protection laws, and strict liability based on defective design." Second, the court below did not merely announce a test and then remand for the district court to apply it, but instead analyzed the claims and dismissed them all, so its full judgment is before this Court. Third, *Cipollone* and *Medtronic* each engaged in an analysis of the state-law claims presented. Fourth, the farmers' discussion of the varying appellate court tests explained why certiorari was warranted, but never suggested the farmers were not challenging the Fifth Circuit's analysis of their claims. Finally, Dow itself does not make this argument, thus acknowledging that the farmers' claims are properly before the Court.

edly acknowledges that the farmers' claims in theory should not be preempted, but argues lamely that they should be foreclosed from an opportunity to prove their claims. Dow's use of the declaratory judgment mechanism should not be allowed to deny the farmers their day in court.

1. *Strict Liability.* Dow relies on its broad inducement theory and ignores that a trial could show that Strongarm's product design was defective *even assuming* its warnings were adequate. As our opening brief explains (at 40-42, 47-48), under Texas law and the Restatement of Torts, warnings do not negate a failure to provide a reasonably safe design.[13]

Dow concedes (at 43) that defective design theories are not preempted, but nonetheless asserts that, because Dow supposedly could have marketed Strongarm in a reasonably safe manner with a different label, all such claims necessarily reduce to a failure to warn. But the farmers allege that Dow could have designed the product in a safer manner to comport with the use claims made on its label. Indeed, a jury verdict based on such evidence plainly would not be rooted in a failure to warn, but rather in Dow's failure to design Strongarm in a reasonably safe manner. A properly designed herbicide could thus retain the 2000 label's use instruction. *See Restatement (Third) of Torts: Product Liability* § 2 (1998) (explaining three independent theories of defect based on "manufacturing," "design," or "inadequate instructions or warnings"); *Turner v. General Motors Corp.*, 584 S.W.2d 844, 847 (Tex. 1979) (same). This Court should reject Dow's broad theory, which would allow a manufacturer to market an unsafe pesticide that it reasonably could have designed in a safer manner with a label that far exceeded what the product could deliver, and then claim immunity from damages under FIFRA because it could have used different label instructions.[14]

[13] The lower courts were in such a rush to dismiss this case that they did so despite the fact that Dow's motion for summary judgment (C.A. Rec. 262-325) did not even mention the farmers' strict-liability claims.

[14] Dow invokes (at 30) cases on the broader question whether damages claims can ever be FIFRA "requirements." But the same decisions have

Dow wrongly claims the farmers defaulted procedurally by not introducing "evidence of a safer, feasible alternative design" or "evidence of a manufacturing or formulation defect." Br. 44; *see also* Texas Chemical Council Br. 5-10. Neither lower court addressed that argument, and this Court should not do so in the first instance. Dow never raised its evidentiary theory in the district court because its summary judgment motion was based solely on preemption (plus a legal argument on limitation of remedies) – not on the merits of the

consistently *refused* to preempt design and manufacturing defect claims not premised on a failure to warn (even though some courts have overreached by applying an "inducement" theory similar to the court of appeals here). *See, e.g.*, *Worm v. American Cyanamid Co.*, 970 F.2d 1301, 1307 (4th Cir. 1992) ("[W]e fail to see how a state-imposed standard of care relating to product design, manufacture, testing, and the like, can qualify as a labeling requirement under FIFRA."); *In re DuPont-Benlate Litig.*, 859 F. Supp. 619, 623 (D.P.R. 1994) ("[A]llegations that Benlate was defective or inadequately designed can continue to be litigated, while the claim that DuPont failed to warn consumers about the defect or inadequate design is preempted."); *Dow Chem. Co. v. Ebling*, 723 N.E.2d 881, 900-02 (Ind. Ct. App. 2000) (FIFRA does "not preempt strict product liability claims relating to product design, manufacturing or testing as long as they are not based on inadequacy in the product's labeling or packaging."), *vacated on other grounds*, 753 N.E.2d 633 (Ind. 2001).

In any event, the cases prior to *Cipollone* generally held that failure to warn claims (and other claims against pesticide manufacturers) were not preempted under FIFRA, so the law for 20 years after the 1972 Act generally favored *non*-preemption. *See, e.g.*, *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1541 (D.C. Cir. 1984) (affirming state-law wrongful death verdict against pesticide manufacturer over preemption defense). That was also true of district court decisions. *See, e.g.*, *Montana Pole & Treating Plant v. I.F. Laucks & Co.*, 775 F. Supp. 1339, 1344 (D. Mont. 1991) (denying motion to dismiss because "FIFRA does not impliedly preempt state common law tort claims against manufacturers of EPA-registered pesticides"), *aff'd*, 993 F.2d 676 (9th Cir. 1993) (without discussing FIFRA issue). *See generally* 101 ALR Fed. 887 (1991) (collecting pre-*Cipollone* FIFRA preemption cases); Pet. Br. 42 n.30. Post-*Cipollone* cases have largely ignored *Medtronic*'s more apposite analysis of "requirements" under a statute more analogous to FIFRA than the 1969 Tobacco Act, and upheld preemption under the same type of "requirements" *uber Alles* approach advanced by Dow. *See* Dow Br. 27 n.17.

farmers' claims. *See* C.A. Rec. 264-324 (entitled "Motion for Summary Judgment on Principles of Federal Pre-emption and the Uniform Commercial Code"). As Dow has acknowledged, "no pre-trial discovery was undertaken in this case." Dow Cert. Opp. 3.[15] It would therefore be inappropriate to require the farmers to have produced "evidence" in support of their claims before discovery is permitted. *See Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 512 (2002).

2. *Express Warranty*. Dow admits (at 44) it went further than merely providing the required directions for use by stating that it "warrants" Strongarm for those uses. As this Court held in *Cipollone*, such voluntary warranties are not preemptive "requirements." Pet. Br. 42-44. The off-label warranty claims based on Dow's representations that Strongarm was "excellent" for use on West Texas peanuts would thus survive even if Dow were correct that they added nothing to the label's express warranty; in addition, such off-label claims are never preempted because they are not made on the "labeling" as required by § 136v(b). *See* § 136(p) (defining "label" and "labeling"); Pet. Br. 44-45.[16]

3. *Fraud/Deceptive Trade Practices*. Dow claims that the Court's *Cipollone* analysis (*see* Pet. Br. 46-47) is inapplicable because § 136v(b) preemption "does not turn on the source of the legal duty," but rather on the effect of the remedy. Dow Br. 46. That assertion cannot be squared with this Court's holding that fraud claims based on statements in advertising were not preempted even though the 1969 Tobacco Act generally preempted "requirement[s]" "with respect to . . . adver-

[15] Dow filed its summary judgment motion based on preemption soon after filing its complaint, and one day after the district court denied the farmers' motion to dismiss for lack of jurisdiction. *See* JA 2.

[16] Dow wrongly asserts that its representations would be considered inactionable "puffing" as a matter of Texas law. *See Helena Chem. Co. v. Wilkins*, 47 S.W.3d 486, 502-04 (Tex. 2001) (rejecting puffery defense and affirming jury verdict on seller's false and misleading claims that grain sorghum seeds would be "excellent" for plaintiff farmers' lands). In any case, neither of the courts below addressed this state-law issue.

tising." *Cipollone*, 505 U.S. at 515. A duty not to mislead does not impose a relevant labeling requirement. And fraud claims based on Dow's off-label statements are clearly not preempted, because § 136v(b) is limited to "labeling or packaging" requirements. As Justice O'Connor's *Medtronic* opinion explained, "[w]here a state cause of action seeks to enforce a [federal] requirement," the federal law "does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*." 518 U.S. at 513 (concurring in part).

4. *Negligence*. Dow now admits (at 43, 47) that manufacturing defect (both negligent and strict liability) and negligent-testing claims are not preempted. Those concessions compel a remand, as the farmers' claims allege such negligence. *See* Pet. Br. 47-48.[17] Discovery could well establish that Dow simply goofed in testing Strongarm and in mixing the batches of Strongarm sold to the farmers. Dow incorrectly contends (at 47) that the farmers' negligent-testing claims necessarily reduce to a failure to warn. Its argument rests on the same fallacy as Dow's arguments on the strict liability claims: the fact that a different label warning might

[17] Dow's assertion (at 47) that the farmers did not allege a claim that could encompass, for example, "contaminat[ion] in the manufacturing process," is belied by the complaint's allegation of negligence in the "development, testing, *manufacture*, *production* and promotion of Strongarm." JA 185 (emphasis added); *see* Pet. Br. 47. Only discovery can reveal whether the failure of Strongarm is due to a manufacturing defect, because information about Dow's manufacturing operations and processes is in its sole possession – as Dow acknowledged when addressing the manufacturing-defect theory in its summary judgment motion. *See* C.A. Rec. 311 ("If a particular lot number is identified, Dow AgroSciences can produce the retainer samples and demonstrate compliance with all product specifications and the EPA-approved confidential statement of formula."); *id.* at 367-69 (Dow affidavit addressing manufacturing-defect theory). Although this case is before the Court on Dow's summary judgment motion, that motion was based solely on preemption; Dow did *not* move for summary judgment on the merits of the farmers' claims. Thus, the Court "must accept as true all of the factual allegations contained in the complaint." *Swierkiewicz*, 534 U.S. at 508 n.1.

have made the product safe for use as originally designed (or persuaded the farmers not to use it at all) does not change the fact that Dow could have formulated its product differently to make it safe for use in West Texas and in compliance with its label. Dow wrongly contends (at 47) that the "central piece of evidence" for negligent testing was its own 180-degree flip-flop in its supplemental label, and so the negligent testing claim therefore also morphed into a failure-to-warn claim. The farmers were never given the opportunity to develop evidence of their negligent-testing claims. Although Dow's rush to change its label evidences that Strongarm was unsuited for the market in 2000, use of that fact does not transform the farmers' claims into preempted failure-to-warn claims.

III. THE POST-USE CLAIMS ARE NOT PREEMPTED

Dow concedes that the post-sale, off-label claims are not preempted but wrongly claims the farmers "did not challenge the district court's limitation-of-remedies ruling in the court of appeals." Br. 50. In fact, the farmers argued that issue in detail in their Fifth Circuit brief, *see* Pet. C.A. Br. 57-60, and Dow joined issue, *see* Resp. C.A. Br. 57-62. Indeed, an "issue presented" by Dow was whether "certain provisions on the Strongarm label are valid and enforceable limitations on the available remedy for . . . alleged post-application representations." *Id.* at 2; *see also id.* at 6 (summary of argument).

Nothing in FIFRA required Dow to place a limitation-of-remedies provision on the label, and Dow acknowledges here that FIFRA does not preempt these post-use claims. Nor does Dow contest the black-letter rule in Texas that a limitation of liability for fraud is void. *See* Pet. Br. 47 n.34, 49 n.35. Accordingly, the Court should reject Dow's erroneous waiver argument and remand for further proceedings on whether, as a matter of state law, the label's limitation-of-liability provision could immunize Dow's false off-label statements.

CONCLUSION

The court of appeals' judgment should be reversed.

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DENNIS BATES, ET AL., PETITIONERS

v.

DOW AGROSCIENCES LLC

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENT

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QUESTION PRESENTED

Whether the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.*, preempts petitioners' state tort claims alleging that application of respondent's herbicide damaged petitioners' peanut crops.

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Notice 96-4 (June 3, 1996)	21, 23
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In the Supreme Court of the United States

No. 03-388

DENNIS BATES, ET AL., PETITIONERS

v.

DOW AGROSCIENCES LLC

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENT

INTEREST OF THE UNITED STATES

The United States, through the Environmental Protection Agency (EPA), has responsibility for implementing and enforcing the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* FIFRA generally requires that EPA must register a pesticide and approve its label before that pesticide may be distributed, sold, or used in any State. 7 U.S.C. 136a. States retain power to restrict the distribution, sale, or use of pesticides within their borders, but they cannot "impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. 136v(b). The United States, which filed a brief amicus curiae at the Court's invitation in response to the petition for a writ of certiorari, has a strong interest in preserving Congress's express delineation of federal and state authority, which ensures that the federal government can establish and maintain nationally uniform requirements for labeling and packaging.

STATEMENT

A. The Federal Insecticide, Fungicide, And Rodenticide Act

1. Congress created FIFRA through a series of enactments to regulate the labeling, sale, and use of pesticides, including herbicides. See *Wisconsin Pub. Intervenor* v. *Mortier*, 501 U.S. 597, 601 (1991). As originally enacted in 1947, see ch. 125, 61 Stat. 163, FIFRA "was primarily a licensing and labeling statute." *Mortier*, 501 U.S. at 601 (quoting *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. 986, 991 (1984)). In 1972, Congress "significantly strengthened FIFRA's registration and labeling standards" in response to "environmental and safety concerns." *Ibid.* See Federal Environmental Pesticide Control Act of 1972 (1972 Amendments), Pub. L. No. 92-516, 86 Stat. 973. In addition, Congress amended FIFRA to "regulate the use, as well as the sale and labeling, of pesticides," 501 U.S. at 601 (quoting *Ruckelshaus*, 467 U.S. at 991-992), and granted EPA (which, beginning in 1970, had been charged with federal oversight of pesticide programs) "increased enforcement authority." *Ibid.* The 1972 Amendments effectively "transformed FIFRA from a labeling law into a comprehensive regulatory statute." *Ibid.* (quoting *Ruckelshaus*, 467 U.S. at 991). Congress has continued to amend FIFRA in response to experience gained in regulating pesticides. See, *e.g.*, Federal Pesticide Act of 1978 (1978 Amendments), Pub. L. No. 95-396, 92 Stat. 819; Food Quality Protection Act of 1996 (1996 Amendments), Pub. L. No. 104-170, Tit. II, 110 Stat. 1493.

2. The 1972 Amendments revamped Section 136a of FIFRA and established a detailed program for EPA to register pesticides for particular uses and to approve the associated pesticide labels. 7 U.S.C. 136a. Section 136a(c)(5) of FIFRA provides that EPA "shall register a pesticide" if

the agency determines, in light of any restrictions placed on the pesticide's use, that:

> (A) its composition is such as to warrant the proposed claims for it;
>
> (B) its labeling and other material required to be submitted comply with the requirements of this subchapter;
>
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
>
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

7 U.S.C. 136a(c)(5). EPA has promulgated regulations implementing FIFRA's requirements. See 40 C.F.R. 152 *et seq.* If a pesticide manufacturer fails to comply with the registration requirements, EPA may issue "stop sale, use, or removal" orders, 7 U.S.C. 136k(a), the offending products may be seized and condemned, 7 U.S.C. 136k(b), and the pesticide manufacturer may be subject to civil and criminal penalties, 7 U.S.C. 136*l*. See 7 U.S.C. 136j (identifying "[u]nlawful acts").

3. EPA interpreted FIFRA's direction that EPA consider whether the pesticide's "composition is such as to warrant the proposed claims for it" (7 U.S.C. 136a(c)(5)(A)) to require EPA to evaluate the "efficacy" of the pesticide. Based on its experience following the 1972 Amendments, EPA reported to Congress in 1977 that the agency's obligation under Section 136a(c)(5) to evaluate efficacy claims in the registration process was diverting scarce resources needed to evaluate environmental and health effects. Congress responded in the 1978 Amendments, providing:

> In considering an application for the registration of a pesticide, the Administrator [of EPA] may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy.

§ 5, 92 Stat. 825 (7 U.S.C. 136a(c)(5)). As a consequence of the 1978 Amendments, EPA "has waived all requirements to submit efficacy data" for pesticide products except those aimed at controlling certain "pest microorganisms that pose a threat to human health." 40 C.F.R. 158.640(b)(1). EPA's regulations make clear, however, that "each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices." *Ibid.* Moreover, EPA "reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration." *Ibid.* See 40 C.F.R. 158.540; 47 Fed. Reg. 53,192 (1982); 44 Fed. Reg. 27,932, 27,938 (1979) (col. 3). In addition to the requirement that applicants for registration develop and maintain efficacy data, EPA requires the registrant, after a pesticide has been registered, to report certain incidents of harm to non-target organisms, such as crops. 40 C.F.R. 159.184.

4. FIFRA's regulatory program encourages federal-state cooperation in regulating pesticides. See *Mortier*, 501 U.S. at 601-602. Section 136v, captioned "Authority of States," sets out key principles of that relationship. See 7 U.S.C. 136v. Section 136v(a) recognizes that, as a general matter, States retain their historic authority to regulate pesticide sale or use, provided that a State does not permit a

sale or use that FIFRA, or EPA's implementing regulations, prohibit:

> **(a) In general**
>
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

7 U.S.C. 136v(a). Nevertheless, to ensure a uniform nationwide approach to pesticide labeling, Section 136v(b) provides a specific limitation on a State's authority with respect to the content of pesticide labeling:

> **(b) Uniformity**
>
> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

7 U.S.C. 136v(b). Section 136v(c)(1) further provides that a State shall have the power, subject to various limitations, to allow additional uses of federally registered pesticides within the individual State's borders:

> **(c) Additional uses**
>
> (1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this subchapter and if registration for such use has not previously been denied, disapproved, or cancelled by the Administrator.

7 U.S.C. 136v(c)(1). Section 136v(c)(2) through (4) sets out additional limitations on state-issued registrations. 7 U.S.C. 136v(c)(2)-(4).

In short, Section 136v provides that a State may prohibit the sale or use of any pesticide within its borders. Under

specified conditions, a State may also allow a pesticide to be used within its borders for purposes other than those provided in the federal registration. A State may not, however, "impose * * * any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. 136v(b).

B. The Facts And Proceedings Below

1. Petitioners are twenty-nine Texas peanut farmers who claim that respondent Dow Agrosciences LLC's Strongarm herbicide harmed their crops. Pet. App. 1a-2a. They sent respondent letters in accordance with the Texas Deceptive Trade Practices Act (DTPA), Tex. Bus. & Com. Code Ann. § 17.505(a) (West 2002), which provides that plaintiffs seeking judicial relief under the DTPA must give the defendant sixty days' notice before bringing suit. In their notice letters, petitioners stated that, unless respondent provided compensation, petitioners would bring suit for false advertising, breach of warranty, and fraudulent trade practices under the DTPA. Pet. App. 3a.

Before the notice period elapsed, respondent filed suit against petitioners in the United States District Court for the Northern District of Texas. Alleging diversity jurisdiction, respondent sought a declaratory judgment that: (1) FIFRA preempts all of petitioners' state law claims; (2) a paragraph on the Strongarm label, entitled "Limitation of Remedies," restricted petitioners' remedies to reimbursement of the purchase price of the Strongarm product; and (3) a paragraph on the Strongarm label, entitled "Warranty Disclaimer," barred petitioners' warranty claims. Petitioners filed counterclaims alleging negligence, breach of implied and express warranties, fraud in the inducement, defective design, estoppel, and waiver. Pet. App. 3a.[1]

[1] Petitioners also filed separate actions in Texas state court against respondent. Those cases were abated by the Texas state court pending resolution of respondent's action in federal district court. Following the court of appeals' decision, there seem to have been some efforts by petitioners or parties associated with them to revive the state court actions. Respondent obtained a federal court injunction barring petitioners and those in privity with them from pursuing the state court actions. *Dow Agrosciences* v. *Bates*, No. Civ. A. 5:01-CV-331-C, 2003 WL 22660741 (N.D. Tex. Oct. 14, 2003). Petitioners have appealed that order to the Fifth Circuit, which has stayed all proceedings pending this Court's decision in this case. *Dow Agrosciences* v. *Bates*, No. 03-11205 (July 13, 2004).

2. The district court granted summary judgment for respondent. Pet. App. 21a-31a. The court ruled that Section 136v(b) of FIFRA preempted petitioners' negligence and warranty claims because those claims, at bottom, challenged the statements that respondent placed on the Strongarm label. *Id.* at 25a-26a, 30a. The court also held that Section 136v(b) preempted petitioners' fraud claims because those claims were based on alleged statements of respondent's employees and distributors that merely repeated information appearing on the Strongarm label. *Id.* at 27a-28a. Finally, the district court ruled that petitioners' implied warranty claims and claims based on alleged oral statements of respondent's employees and distributors that went beyond the label statements were barred by the express disclaimers that respondent placed on the Strongarm label. *Id.* at 26a-27a, 28a-30a.

3. The court of appeals affirmed. Pet. App. 1a-20a. The court first rejected contentions that the federal courts lacked subject matter jurisdiction because the claims of some of the petitioners did not meet the amount-in-controversy requirement of 28 U.S.C. 1332(a). Pet. App. 3a-5a. The court of appeals next rejected the argument that the district court abused its discretion by not abstaining from exercising jurisdiction in favor of a state court action brought by petitioners. *Id.* at 4a-5a, 8a. Petitioners have not sought further review of those determinations in this Court.

The court of appeals then turned to the question of federal preemption. The court concluded that this case turns on

whether Section 136v(b) of FIFRA, which prohibits States from imposing "any requirements for labeling or packaging in addition to or different from those required under [FIFRA]," 7 U.S.C. 136v(b), expressly preempts petitioners' state law claims. Pet. App. 9a-11a. The court rejected petitioners' arguments that "state labeling requirements related to product effectiveness are not within the scope of FIFRA's express preemption clause" and that the particular claims at issue here are not subject to express preemption because they "are not sufficiently related to the content of the Strongarm label." *Id.* at 11a; see *id.* at 12a-15a, 15a-19a.

a. The court rejected petitioners' contention that FIFRA does not preempt product efficacy claims, as opposed to product safety claims, reasoning that Section 136v(b) expressly preempts "any requirement for labeling" that is "in addition to or different from" what FIFRA requires, without reference to the subject matter of the labeling requirement. Pet. App. 12a-13a. The court noted that "FIFRA's text does not define the scope of FIFRA's preemption clause to be a function of existing EPA regulations." *Id.* at 13a. Rejecting petitioners' reliance on *American Cyanamid Co.* v. *Geye*, 79 S.W.3d 21 (Tex. 2002), cert. denied, 539 U.S. 969 (2003), the court concluded that Section 136v(b) expressly preempts any state court action that would result in imposing a labeling requirement "in addition to or different from" (7 U.S.C. 136v(b)) the requirements imposed through EPA approval of the product label under FIFRA, regardless of the scope of the product evaluation that EPA conducts in the course of approving the label. Pet. App. 14a-15a.

b. The court of appeals analyzed whether Section 136v(b) preempted the specific claims at issue by examining "whether a judgment against [respondent] would cause it to need to alter the Strongarm label." Pet. App. 16a; see *id.* at 15a-19a. The court concluded that Section 136v(b) preempted petitioners' breach-of-warranty and fraud-related claims because those claims were predicated on alleged "off

label" representations that did not differ in "any material manner" from the Strongarm label. *Id.* at 16a-17a. The court reasoned that imposing liability would, as a practical matter, force respondent to alter its label. *Ibid.* The court concluded that Section 136v(b) preempted petitioners' defective design and negligence claims because each was "a disguised claim for failure to warn" that, if successful, would similarly force respondent to change its label. *Id.* at 18a-19a.

SUMMARY OF ARGUMENT

A. FIFRA prohibits States from imposing "any requirements" for pesticide labeling that are "in addition to or different from" those required under FIFRA. 7 U.S.C. 136v(b). The plain terms of that prohibition expressly preempt state pesticide labeling requirements, regardless of whether those requirements are expressed through positive enactments or common-law duties. See *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992). Neither the structure of Section 136v(b), nor the purposes or legislative history of FIFRA, provides a persuasive basis for categorically exempting state common-law requirements from preemption. Rather, Section 136v(b) preempts any state common-law duties that would compel the manufacturer of a pesticide registered under FIFRA to change its EPA-approved label to avoid liability.

B. Section 136v(b) does not exempt from preemption state labeling requirements pertaining to pesticide efficacy. EPA generally does not require an applicant for pesticide registration to submit efficacy data in the course of the FIFRA registration process, but that fact does not alter Section 136v(b)'s preemptive effect. FIFRA continues to impose labeling requirements respecting product efficacy. There accordingly is no basis for distinguishing, for purposes of applying Section 136v(b)'s express preemption provision, label requirements respecting product efficacy from other

label requirements addressing, for example, safety, health, or environmental concerns.

C. Section 136v(b) also does not exempt from preemption common law duties, such as those prohibiting "false or misleading" statements, that are facially "consistent with" FIFRA's misbranding prohibitions. State common-law standards, even if nominally identical to FIFRA's misbranding prohibitions, are applied by judges and juries. The application of those standards in 50 state jurisdictions would invariably result in inconsistent labeling requirements and undermine FIFRA's central goal of promoting uniform labeling requirements.

D. Petitioners did not ask this Court to review the court of appeals' affirmance of the district court's determination that petitioners' particular state-law claims are "label-related," in the sense that petitioners' success on those claims would compel a pesticide manufacturer to change the label on its product in order to avoid future liability. The Court accordingly should not reach those issues, which turn on a case-specific evaluation of the factual allegations and the particular characteristics of the claims for relief.

ARGUMENT

FIFRA PRECLUDES STATE TORT CLAIMS THAT WOULD SUBJECT PESTICIDE MANUFACTURERS TO INCONSISTENT PRODUCT LABELING REQUIREMENTS

A. Section 136v(b) Preempts State Common-Law Duties That Would Impose Requirements For Labeling "In Addition To Or Different From" Those Required Under FIFRA

FIFRA forbids States from imposing "any requirements" for pesticide labeling "in addition to or different from" those required under FIFRA. 7 U.S.C. 136v(b). The statutory term "any requirements" includes both positive state regu-

lation and indirect regulation through state common-law tort actions. As the court of appeals correctly held, therefore, Section 136v(b) preempts state common-law duties that would have the effect of compelling the manufacturer of a pesticide registered under FIFRA to change its EPA-approved label in order to avoid liability.

1. *Section 136v(b) expressly preempts both state regulatory requirements and state common-law duties*

Section 136v(b) broadly and expressly prohibits "any requirements for labeling" that are "in addition to or different from" those that FIFRA imposes. 7 U.S.C. 136v(b). Section 136v(b)'s plain text does not distinguish among state labeling requirements based on their origin in a state legislature's enactment of statutes, a state agency's promulgation of rules, or a state court's articulation of common-law standards of care. All state labeling requirements, regardless of their source, are preempted.

This Court's decision in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992), confirms the plain meaning of Section 136v(b)'s unambiguous prohibition. The Court ruled in *Cipollone* that a provision of the Public Health Cigarette Smoking Act of 1969, 15 U.S.C. 1331 *et seq.*, proscribing the imposition of any tobacco advertising "requirement or prohibition * * * under State law," encompasses not only state statutes and regulations, but also state common-law duties enforced through tort actions. See 505 U.S. at 521-523 (plurality opinion of Stevens, J.); *id.* at 548-549 (Scalia, J., concurring in part). On this issue, "[t]here is no notable difference between the language in the 1969 Cigarette Act and the language in FIFRA." *Taylor AG Indus.* v. *Pure-Gro*, 54 F.3d 555, 559 (9th Cir. 1995). In each instance, the plain terms of a federal statute's express preemption provision precludes state common-law tort actions based on

alleged labeling deficiencies. See Pet. App. 12a & n.11 (citing additional decisions).

This Court's decision in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), further fortifies that conclusion. The Court ruled in *Medtronic* that the Food and Drug Administration's (FDA's) approval of a pacemaker under relevant provisions of the Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539 (21 U.S.C. 360c *et seq.*), did not, under the particular circumstances presented, preempt a state-law action alleging that the pacemaker was improperly designed. See 518 U.S. at 492-494. The separate *Medtronic* opinions recognized, however, that the MDA's provisions prohibiting the States from establishing any inconsistent "requirement" that "relates to the safety or effectiveness of the device," 21 U.S.C. 360k(a), could preempt state-law damage suits. See 518 U.S. at 504 (Breyer, J., concurring in part); *id.* at 509-512 (O'Connor, J., concurring in part and dissenting in part); see also *id.* at 502 (opinion of Stevens, J.).

This Court has correctly recognized that Congress could not have intended the anomalous consequences that would result if federal statutes that preempt inconsistent state "requirements" were construed to reach state agency regulations but exclude state common-law duties. As Justice Breyer's separate opinion in *Medtronic* explained in comparing regulations and common-law duties that address the same subject matter:

> The effects of the state agency regulation and the state tort suit are identical. To distinguish between them for pre-emption purposes would grant greater power (to set state standards "different from, or in addition to," federal standards) to a single state jury than to state officials acting through state administrative or legislative law-making processes.

518 U.S. at 504. The lower courts have followed this Court's guidance in *Cipollone* and *Medtronic*. They have ruled, with

near unanimity, that Section 136v(b)'s prohibition of state labeling requirements preempts state requirements imposed through common-law duties and precludes state tort actions based on inadequate labeling.[2]

2. *Section 136v(b) does not indirectly exempt state common-law duties from preemption*

Petitioners contend that Section 136v(b) can be construed in a manner that would "not compel" preemption of state common-law duties. Pet. Br. 16-25. Petitioners essentially ask this Court to reject the plain import of clear text in favor of strained inferences that the lower courts have correctly found unpersuasive.

a. Petitioners first note (Pet. Br. 17) that Section 136v(a) preserves state authority to "regulate the sale or use" of

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[2] Nine federal courts of appeals have ruled that FIFRA expressly preempts state-law based claims that challenge a product's label. *Grenier* v. *Vermont Log Bldgs., Inc.*, 96 F.3d 559 (1st Cir. 1996); *Hawkins* v. *Leslie's Pool Mart, Inc.*, 184 F.3d 244 (3d Cir. 1999); *Lowe* v. *Sporicidin Int'l*, 47 F.3d 124 (4th Cir. 1995); *Kuiper* v. *American Cyanamid Co.*, 131 F.3d 656 (7th Cir. 1997), cert. denied, 523 U.S. 1137 (1998); *Netland* v. *Hess & Clark Inc.*, 284 F.3d 895 (8th Cir.), cert. denied, 537 U.S. 949 (2002); *Nathan Kimmel, Inc.* v. *DowElanco*, 275 F.3d 1199 (9th Cir. 2002); *Arkansas-Platte & Gulf P'ship* v. *Van Waters & Rogers, Inc.*, 959 F.2d 158 (10th Cir. 1992), aff'd after remand, 981 F.2d 1177 (10th Cir.), cert. denied, 510 U.S. 813 (1993); *Lowe's Home Ctrs., Inc.* v. *Olin Corp.*, 313 F.3d 1307 (11th Cir. 2002). Only the D.C. Circuit, in *Ferebee* v. *Chevron Chem. Co.*, 736 F.2d. 1529, 1540-1541, cert. denied, 469 U.S. 1062 (1984), has held to the contrary. The D.C. Circuit premised its *Ferebee* decision, which pre-dated *Cipollone*, on the conclusion that "requirements" did not include common-law duties. Although the D.C. Circuit has not revisited its *Ferebee* decision, it embraced *Cipollone*'s reasoning in *Waterview Management Co.* v. *FDIC*, 105 F.3d 696 (D.C. Cir. 1997). Eighteen state supreme courts have held that FIFRA preempts state tort actions. See Resp. Br. in Opp. 16-17 n.15. But see *Sleath* v. *West Mont. Home Health Servs., Inc.*, 16 P.3d 1042, 1051-1053 (Mont. 2000), cert. denied, 534 U.S. 814 (2001) (holding that FIFRA does not preempt state tort actions); *American Cyanamid Co.* v. *Geye*, 79 S.W.3d 21 (Tex. 2002), cert. denied, 539 U.S. 969 (2003) (holding that FIFRA does not preempt state tort actions alleging the product is ineffective).

federally registered pesticides, while Section 136v(b) prohibits state "requirements for labeling or packaging." 7 U.S.C. 136v(a) and (b). Petitioners argue that Section 136v(a) should be viewed as identifying a class of permissible state "regulat[ions]"—supposedly limited to "positive enactments"—while Section 136v(b) should be viewed as prohibiting a "subset" of those positive enactments respecting labeling. Pet. Br. 17-18. Section 136v's text, however, does not support that construction.

Section 136v(a) and Section 136v(b) are independent provisions that contain separate, stand-alone commands. The provisions are linked only insofar as Section 136v(a) provides that "[a] State" may regulate sale and use, while Section 136v(b) provides that "[s]uch State" shall not impose labeling requirements. That syntax indicates that Sections 136v(a) and 136v(b) give direction to the same entities—"States." But it does not suggest that the two provisions address the same set of laws such that, if Section 136v(a) embraces only "positive enactments," then Section 136v(b)'s "requirements" must be a "subset" of those "positive enactments." If Congress had intended the construction that petitioners urge, it would have linked not just the relevant entity (*viz.*, the "State") but the laws as well (*e.g.*, by referring to "regulations" in subsection (a) and "such regulations" in subsection (b)). In fact, Section 136v does not expressly link the laws addressed in subsection (a) and those addressed in subsection (b), and it does not use the precise term "regulations" in either subsection.[3]

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[3] Contrary to petitioners' suggestion (Pet. Br. 18), there is nothing "unnatural" in recognizing that FIFRA's labeling requirements, which are expressed in the form of statutory and regulatory provisions, preempt state requirements, whether expressed in the form of positive enactments or common law duties. "There is, of course, 'no federal general common law.'" *Texas Indus., Inc.* v. *Radcliff Materials, Inc.*, 451 U.S. 630, 640 (1981) (quoting *Erie R.R.* v. *Tompkins*, 304 U.S. 64, 78 (1938)). Consequently, federal requirements generally take the form of statutes or regulations, while state requirements may arise from positive enactments or common-law duties. Section 136v(b) quite naturally uses the terms "requirements" and "required" to accommodate the full range of federal and state legal obligations, whatever form they might take.

b. Petitioners contend that "it makes no sense" (Pet. Br. 18-19), in light of Section 136v(a)'s preservation of state authority to ban the sale or use of a pesticide, to construe Section 136v(b) to deny the State the "lesser" authority to impose common-law liabilities for alleged labeling deficiencies. Congress's concern in Section 136v(b), however, is national uniformity and certainty in labeling. If a State bans a pesticide manufacturer from selling a particular product within that State's borders, the ban does not interfere with the federal objective of ensuring that pesticide manufacturers are subject to a single body of labeling requirements and can generally use the same label in every State. But if each State could subject a pesticide manufacturer to liability based on common-law duties respecting labeling that are peculiar to that State, then the federal objective of uniformity would be frustrated. Section 136v(b) addresses that problem by prohibiting States from imposing labeling requirements, whether through positive enactment or through the common law.

c. Petitioners also contend (Pet. Br. 19-20) that there is nothing objectionable about allowing a State to employ common-law liabilities to force pesticide manufacturers to revise their labels because a State can employ its reserved powers under Section 136v(a) to achieve the same end.[4] Specifically, petitioners suggest that a State might induce a manufacturer to revise a pesticide label by threatening to

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[4] Petitioners also cite (Pet. Br. 19) the authority that FIFRA grants to States, under Section 136v(c) and associated regulations, to register additional uses of a pesticide. See 7 U.S.C. 136v(c). States that act under Section 136v(c) are essentially standing in EPA's shoes in exercising FIFRA registration authority, however, so it is not surprising that EPA regulations grant States, in that narrow instance, label review authority similar to EPA's authority.

prohibit the sale or use of the product under Section 136v(a). Petitioners err in suggesting that such state action would necessarily be permissible under Section 136v(b), which by its nature limits the authority otherwise preserved for the States by Section 136v(a). Any state "sale or use" regulation that was adopted with the purpose and effect of compelling a pesticide manufacturer to change its EPA-approved label could well be preempted by Section 136v(b), because it could be construed as amounting to a labeling requirement "in addition to or different from" those imposed under FIFRA. Petitioners' contrary reading of FIFRA would permit States to eviscerate the limitations set forth in Section 136v(b) at will by the simple device of restating their label-related requirements as "sale or use" regulations. See *United States* v. *United Cont'l Tuna Corp.*, 425 U.S. 164, 169 (1976) ("[w]e should * * * be * * * hesitant to infer that Congress intended to authorize evasion of a statute at will").

d. Petitioners invoke (Pet. Br. 21-22) the general statement that "Congress does not cavalierly pre-empt state-law causes of action." *Medtronic*, 518 U.S. at 485. But that observation is merely the starting point of the analysis and of little help in interpreting an *express* preemption provision. Congress's intent "'is the ultimate touchstone' in every pre-emption case," *id.* at 485 (quoting *Retail Clerks Int'l Ass'n, Local 1625* v. *Schermerhorn* 375 U.S. 96, 103 (1963)), and "Congress's intent, of course, primarily is discerned from the language of the pre-emption statute and the 'statutory framework' surrounding it," *id.* at 486 (quoting *Gade* v. *National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part)). Section 136v(b)'s language—particularly its use of the term "requirements"—is sufficiently clear to establish Congress's intent to preempt common law duties respecting pesticide labeling. See *Cipollone*, 505 U.S. at 522 (opinion of Stevens, J.); *id.* at 548-549 (Scalia, J., concurring in part). See pp. 11-13, *supra*.

e. Petitioners contend that FIFRA employs the term "requirements" outside of Section 136v(b) to refer to "direct commands arising out of statutory or regulatory enactments." Pet. Br. 22. They argue (*id.* at 22-25) that Section 136v(b) should be construed consistently with that usage. But even if petitioners' characterization is accurate, such usage does not demonstrate that Congress intended to limit the term to a subset of its ordinary meaning in Section 136v(b). As this Court has explained, the term "requirements" is naturally understood to embrace both positive enactments and common-law duties, see pp. 11-13, *supra*, and it is therefore unsurprising that it can be used to refer to either or both types of legal rules depending on the context in which it is used. For the reasons already stated, Section 136v(b) employs the term in a context that embraces both positive enactments and common-law duties. See pp. 13-14, *supra*.[5]

Petitioners ignore the reality that, if Congress had intended to preserve state common-law actions challenging the adequacy of pesticide labeling, it would have said so. Congress could have stated that only state laws and regulations

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[5] FIFRA's references to federal "requirements" necessarily identify federal statutory or regulatory provisions because "[t]here is, of course, 'no federal general common law.'" *Texas Indus.*, 451 U.S. at 640 (quoting *Erie R.R.*, 304 U.S. at 78). See Pet. Br. 22-23. Thus, it is hardly probative that FIFRA does not use the term to refer to common-law duties in discussing *federal* requirements—the vast majority of the uses identified by petitioners. The one specific reference to state requirements identified by petitioners involves a provision authorizing States to establish "minimum requirements for training" certain personnel. *Id.* at 24 (citing 7 U.S.C. 136w-5). Such requirements, unsurprisingly, are invariably set out as positive enactments. See Pet. Br. 24. Section 136v(b), by contrast, uses the term "requirements" in the context of preemption, where "[t]he effects of the state agency regulation and the state tort suit are identical." *Medtronic*, 518 U.S. at 504 (Breyer, J., concurring in part). In that context, the term "requirements" naturally encompasses positive enactments and common-law duties. See pp. 12-13, *supra*.

are preempted. See *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 58-59, 63 (2002) (addressing the Federal Boat Safety Act of 1971, 46 U.S.C. 4301 *et seq.*). Or Congress could have enacted a savings clause that expressly disclaimed any intent to preempt tort actions. See *id.* at 59, 63; *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 867-868 (2000) (addressing the National Traffic and Motor Vehicle Safety Act of 1966, 15 U.S.C. 1381 *et seq.* (1988)). Congress did neither. Instead, it employed language that, as this Court has recognized, expresses the intent to preclude state common-law causes of action.

3. *The legislative history of FIFRA does not establish that Congress intended to preserve state common-law duties respecting pesticide labeling*

Petitioners assert that Section 136v(b) should not be construed to preempt state common-law duties respecting pesticide labeling because FIFRA's legislative history does not express that intention. Pet. Br. 25-27. The Court disposed of a similar argument in *Cipollone*, stating:

> Although portions of the legislative history * * * suggest that Congress was primarily concerned with positive enactments by States and localities * * *, the language of the Act plainly reaches beyond such enactments. "We must give effect to this plain language unless there is good reason to believe Congress intended the language to have some more restrictive meaning." *Shaw* v. *Delta Air Lines, Inc.*, 463 U.S. 85, 97 (1983).

Cipollone, 505 U.S. at 521-522. The absence of legislative history expressing an intent to preclude tort actions reveals nothing and, in any event, cannot overcome the preemptive force of Section 136v(b)'s plain text. *Ibid.* See, *e.g.*, *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374, 385 n.2 (1992) ("[L]egislative history need not confirm the details of changes in the law effected by statutory language before we will interpret that language according to its natural meaning."); *Harrison* v. *PPG Indus., Inc.*, 446 U.S. 578, 592 (1980) ("It would be a strange canon of statutory construction that would require Congress to state in committee reports or elsewhere in its deliberations that which is obvious on the face of a statute.").[6]

Even if this Court were to give weight to the legislative history, it would find that it demonstrates no positive intent to preserve tort actions. To the contrary, the Committee reports supporting Congress's 1972 overhaul of FIFRA contain statements expressing an intent to provide for broad preemption of state requirements respecting pesticide labels. The House Committee Report states, with reference to Section 136v(b), that "the Committee has adopted language which is intended to completely preempt State authority in regard to labeling and packaging." H.R. Rep. No. 511, 92d Cong., 1st Sess. 16 (1971). The Senate Committee Report expresses a similar intent, stating "[Section 136v(b)] preempts any State labeling or packaging requirements differing from such requirements under the Act." S. Rep. No. 838, 92d Cong., 2d Sess. Pt. 1, at 30 (1972). Those statements suggest that Congress envisioned that all

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[6] In *Medtronic*, five Justices found that Congress's use of the term "requirements" clearly reached common-law duties. See 518 U.S. at 511 (O'Connor, J., concurring in part) ("If § 360k's language is given its ordinary meaning, it clearly pre-empts any common-law action that would impose a requirement different from, or in addition to, that applicable under the FDCA—just as it would pre-empt a state statute or regulation that had that effect."); *id.* at 503-504 (Breyer, J., concurring in part and concurring in the judgment) ("The statute's language, read literally, supports that conclusion. * * * One can reasonably read the word 'requirement' as including the legal requirement that grow[s] out of the application, in particular circumstances."). There is no reason to believe that resort to legislative history would have altered those views. See *Mortier*, 501 U.S. at 610 n.4 ("No matter how clearly its report purports to do so, a committee of Congress cannot take language that could only cover 'flies' or 'mosquitoes,' and tell the courts that it really covers 'ducks.'").

"requirements"—whatever their form—would be preempted.

4. *The United States has properly reconsidered and disavowed its prior position that Section 136v(b) does not preempt state common-law duties*

As the United States explained in its brief amicus curiae in *American Cyanamid Co.* v. *Geye*, cert. denied, 539 U.S. 969 (2003), on two earlier occasions in the past, the United States filed briefs as amicus curiae in the lower courts arguing that FIFRA does not preempt certain state-law actions and making some of the same arguments that petitioners and their amici curiae present here. See U.S. Amicus Curiae Br., *Hart* v. *Bayer Corp.*, 199 F.3d 239 (5th Cir. 2000) (No. 98-60496); U.S. Amicus Curiae Br., *Etcheverry* v. *TRI-AG Serv., Inc.*, 993 P.2d 366 (Cal. 2000) (No. S072524). The California Supreme Court rejected the United States' submission. *Etcheverry*, 993 P.2d at 369-377.[7] As the United States explained in its *Geye* brief, the United States reexamined its position in light of the California Supreme Court's ruling in that case, as well as the subsequent rulings of other courts, and concluded that its prior position is incorrect. See U.S. Amicus Curiae Br. at 16-19, *American Cyanamid Co.* v. *Geye*, *supra* (No. 02-367). The United States properly reevaluated its position in light of the considerations expressed in this brief.

B. Section 136v(b) Does Not Exempt From Preemption State Labeling Requirements Pertaining To Product Efficacy

Petitioners contend that, even if Section 136v(b)'s reference to "requirements" includes common-law duties, Section 136v(b) does not preempt their state-law claims because

[7] In *Hart*, the court of appeals ruled that the case had been improperly removed from state court and, therefore, did not address whether the plaintiff's claims were preempted. See 199 F.3d at 243.

those claims are predicated on Strongarm's alleged inefficacy rather than safety, health, or environmental concerns. Pet. Br. 30-37. Specifically, petitioners contend that, because "FIFRA no longer imposes a duty on EPA to evaluate the efficacy of any federally registered pesticide," there are no federal requirements relating to efficacy, and the "'requirements' preempted in section 136v(b), therefore, cannot include claims concerning the efficacy of pesticides." *Id.* at 30.

Petitioners are mistaken. To be sure, EPA generally does not require an applicant for registration to submit efficacy data in the course of the FIFRA registration process. As previously noted (pp. 3-4, *supra*), Congress amended FIFRA in 1978, at EPA's request, to give the agency authority to waive the requirement that applicants submit information demonstrating that their products are efficacious. See 7 U.S.C. 136a(c)(5). EPA has generally waived such requirements and typically does not conduct independent product efficacy evaluations. 40 C.F.R. 158.640(b)(1); see EPA Pesticide Registration Notice 96-4 (June 3, 1996) (J.A. 228-235). But neither the 1978 Amendments, nor EPA's waiver of data requirements, alters Section 136v(b)'s preemption of state requirements respecting pesticide labels.[8]

[8] Furthermore, the issue of EPA's involvement or non-involvement in efficacy matters is not as simple as petitioners would suggest. Although EPA generally does not review efficacy data in registering a pesticide, efficacy issues may receive closer scrutiny in numerous circumstances. For example, EPA may examine efficacy data: (1) in making registration decisions for products not covered by the general data waiver (*e.g.* hospital disinfectants) see 40 C.F.R. 158.640(b)(1); (2) for the purpose of making statutory findings regarding reduced-risk pesticides, see 7 U.S.C. 136a(c)(10), the "public interest," see 7 U.S.C. 136a(c)(7)(C), and the FIFRA risk/benefit standard, see 7 U.S.C. 136(bb); and (3) in evaluating information submitted pursuant to the registrant's continuing obligation to report information bearing on a pesticide's unreasonable adverse effects, see 7 U.S.C. 136d(a)(2); 40 C.F.R. 159.184. Predicating tort preemption on EPA's involvement, or lack thereof, in efficacy determinations could undermine EPA's discretionary decision not to review efficacy data in certain circumstances and lead to frequent, burdensome discovery

The 1978 Amendments did not modify the operative terms of Section 136v(b), which prohibit a state from imposing "any requirements" that are "in addition to or different from" the FIFRA requirements. 7 U.S.C. 136v(b).[9] The 1978 Amendments relieved EPA of any obligation to require applicants for registration to submit efficacy data, or for EPA to review such data on its own, but the 1978 Amendments left in place the requirement that applicants submit accurate product efficacy labeling in the registration process. See 7 U.S.C. 136a(c)(5)(B). For example, EPA requires the applicant to provide directions for use that are "adequate to protect the public from fraud," 40 C.F.R. 156.10(i)(1)(i), and that include "[a]ny limitations or restrictions on use required to prevent unreasonable adverse effects, such as * * * [w]arnings as required against use on certain crops," 40 C.F.R. 156.10(i)(2)(x) and (C).[10]

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demands that would be very intrusive in EPA's regulatory decision-making process.

[9] The 1978 Amendments did alter the language of Section 136v(b) in certain respects that are not relevant here. Those Amendments changed the phrase "labeling and packaging" to "labeling or packaging," and changed the phrase "those required pursuant to this subchapter" to "those required under this subchapter." Compare 7 U.S.C. 136v(b) (1976), with 7 U.S.C. 136v(b) (Supp. II 1978).

[10] While EPA generally does not require applicants to submit efficacy data as part of the initial registration process and does not review efficacy claims, EPA continues to require registrants to develop and maintain data supporting their efficacy claims. 40 C.F.R. 158.640(b)(1); see 40 C.F.R. 158.540. Applicants must provide EPA with that data if the agency so requests, *ibid.*, and in some circumstances (including respondents' initial registration of Strongarm, see U.S. Amicus Curiae Br. on Pet. 16 n.5) must submit it with their registration application. See EPA Pesticide Registration Notice 97-3, § VII(G) (Sept. 4, 1997) (J.A. 252). An applicant must also inform EPA (subject to certain exceptions) if it learns that a registered pesticide has harmed non-target organisms, such as crops or persons. 40 C.F.R. 159.184. Accordingly, EPA continues to exercise oversight of registrants' efficacy claims, and registrants remain obligated to revise their label in light of current information.

Notwithstanding the 1978 Amendments, FIFRA still contains labeling requirements respecting product efficacy, and there accordingly is no reason to distinguish, for purposes of preemption, label requirements respecting product efficacy from label requirements respecting safety, health, or environmental concerns. FIFRA and its implementing regulations specify what a label must contain with respect to "product efficacy," and Section 136v(b) correspondingly bars States from imposing "any requirements for labeling"—including those derived from common-law duties—that are "in addition to or different from those required under [FIFRA]." 7 U.S.C. 136v(b).[11]

C. Section 136v(b) Does Not Exempt From Preemption State Common-Law Duties That Are "Consistent With" FIFRA's Misbranding Prohibitions

Petitioners assert (Pet. Br. 37-39) that Section 136v(b) does not preempt common law duties that result in liability for "false or misleading" statements because those duties are "consistent with" FIFRA's misbranding provisions. See 7 U.S.C. 136(q) (defining "misbranding"); see also 7 U.S.C. 136j(a)(1)(E) (proscribing "misbranding"). Petitioners are mistaken. The State's application of a state-law prohibition

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[11] Petitioners note (Pet. Br. 31, 32) EPA's past statements that pesticide producers remain "potentially subject to damage suits by the user community if their products prove ineffective in actual use." 47 Fed. Reg. at 40,661; see also Pesticide Registration Notice 96-4 (June 3, 1996) (J.A. 230). Those statements are consistent with the numerous court decisions that have held that FIFRA does not preclude all state tort actions, but instead preempts only *label-related* common-law suits. See Pet. App. 10a-11a. Petitioners' reliance (Pet. Br. 35-36) on *Medtronic*'s allowance of some types of tort suits (see 518 U.S. at 492-502) is similarly misplaced. The fact that an express preemption provision does not preclude all tort suits does not diminish the provision's preemptive force with respect to those tort suits that fall within its terms. See *Medtronic*, 518 U.S. at 502.

against "false or misleading statements," even if phrased in general terms similar to FIFRA's misbranding prohibition, would result in the imposition of state "requirements for labeling" that are "in addition to or different from those required under [FIFRA]" (7 U.S.C. 136v(b)).[12]

A comparison of the FIFRA misbranding provisions and the analogous common-law duties demonstrates why this is so. When a pesticide manufacturer submits a FIFRA registration application to EPA, the manufacturer must include "a complete copy of the labeling of the pesticide," 7 U.S.C. 136a(c)(1)(C), that "compl[ies] with the requirements of [FIFRA]," 7 U.S.C. 136a(c)(5), including EPA's detailed labeling requirements, 40 C.F.R. Pt. 156. The manufacturer is subject to federal sanctions if EPA later determines that the registered pesticide is "misbranded." See 7 U.S.C. 136j(a)(1)(E). EPA may determine that a pesticide is misbranded if, among other things, the labeling "bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular," does not provide adequate "directions for use," or omits necessary warnings. 7 U.S.C. 136(q)(1)(A), (F) and

[12] Petitioners incorrectly assert (Pet. Br. 38 n.27) that the United States "endorsed [petitioners'] reasoning" in its *Geye* amicus brief. The United States observed that this Court had ruled in *Medtronic* that the MDA "does not bar common law tort claims that are based on a violation of federal regulations." U.S. Amicus Curiae Br. at 13, *American Cyanamid Co.* v. *Geye*, *supra* (No. 02-367). But the United States explicitly took "no position" in *Geye* "with respect to whether, or what extent" FIFRA preempted the particular claims at issue. *Id.* at 19. Moreover, while it may be permissible for a State to subject a pesticide registrant to common-law liability based on *EPA's* determination that a registrant violated a FIFRA labeling requirement, it would not be permissible for a state court to impose an analogous state-law standard that would result in additional or different labeling requirements, or to purport to enforce a federal standard in factual circumstances that had not been addressed by the expert federal agency charged with ensuring a uniform construction and application of the federal standard.

(G). EPA may pursue a variety of sanctions, including federal stop sale orders, seizure and condemnation of the offending product, and imposition of civil or criminal penalties. See 7 U.S.C. 136j-136*l*. The FIFRA provisions, taken in combination, provide a comprehensive scheme for imposing and enforcing a nationally uniform system of labeling requirements and confer upon EPA the full range of authority to interpret and apply the uniform federal standards.

If a State could subject pesticide manufacturers to the additional state common-law duty to avoid "false or misleading" labeling, with the threat of additional consequences for its violation (including imposition of punitive damages, J.A. 192), the application of that standard would impose "requirements for labeling" that are "in addition to or different from those required under [FIFRA]." FIFRA § 24(b), 7 U.S.C. 136v(b). It is no answer to say that the FIFRA misbranding standard and the state standard of due care are "consistent," because the State is under no obligation under state law to ensure that its common-law standard produces labeling requirements that are the same as those mandated under FIFRA—and absent an EPA finding of misbranding is in no position to do so. EPA administers FIFRA through centralized expert judgment, while the 50 States apply common-law standards through an adversarial process in which lay judges and juries can "reach different decisions on similar facts." *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 871 (2000). Consequently, it is virtually certain that even identically phrased federal and state standards would produce divergent labeling requirements. See *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 242-243 (1959). Pesticide manufacturers would be subject to multiple and inconsistent labeling regimes and would be

forced to abandon or alter EPA-approved labels to avoid liability.[13]

Congress, which expressed its objective in Section 136v(b) to subject pesticide manufacturers to a single body of federal law governing pesticide labeling obligations, could not have intended to undermine that uniformity by allowing each State to determine for itself whether the federally approved label is "false or misleading," and, if so, what remedies and sanctions to impose on the registrant. Rather, Congress prohibited States from imposing additional "requirements for labeling" (7 U.S.C. 136v(b)), including those arising from

[13] Contrary to petitioners' suggestion (Pet. Br. 38-39), this Court's decision in *Medtronic* does not support the notion that FIFRA's misbranding provisions and comparable common-law duties respecting "false or misleading statements" can comfortably coexist. As the Court emphasized, preemption principles must be applied with careful attention to the way in which Congress intended the particular "statute and its surrounding regulatory scheme to affect business, consumers, and the law." 518 U.S. at 486. FIFRA and the MDA are dissimilar in key respects. For example, the Court pointed out in *Medtronic* that "pre-emption under the MDA does not arise directly as a result of the enactment of the statute; rather, in most cases a state law will be pre-empted only to the extent that the FDA has promulgated a relevant federal 'requirement.'" *Id.* at 496. See 21 U.S.C. 360k(a) (preempting state requirements that are different from "any requirement applicable under this subchapter to the device"). FDA's regulations themselves stated that the MDA generally "does not preempt a state or local requirement prohibiting the manufacture of adulterated or misbranded devices" unless "such a prohibition has the effect of establishing a substantive requirement *for a specific device*." 518 U.S. at 499 (quoting 21 C.F.R. 808.1(d)(6)(ii)) (emphasis added). The Court in *Medtronic* explained that "our interpretation of the pre-emption statute is substantially informed by these regulations." *Id.* at 495. In the case of FIFRA, by contrast, preemption can arise directly from FIFRA itself and EPA has enacted no comparable regulation. FIFRA's preemption provision does not contain the "specific device" limitation that the Court discerned in the MDA and FDA's implementing regulations. See *Id.* at 498-501. And even if FIFRA contained such a requirement, EPA's approval of a particular pesticide label would satisfy any such specificity requirement. Accordingly, the Court's observations respecting the MDA are not controlling in this case.

nominally harmonious state common-law standards, in order to avoid the conflict, uncertainty, cost, and potential misinformation that would inevitably result from simultaneous federal and state labeling prescriptions. See *Geier*, 529 U.S. at 871.[14]

D. Petitioners Did Not Seek This Court's Review Of The Court of Appeals' Determination That Their State-Law Claims Would Subject Respondent To Inconsistent Labeling Requirements

Petitioners urged in their petition for a writ of certiorari that the Court should grant review to clarify the legal standard for FIFRA preemption. See Pet. 3. They cited uncertainty over whether FIFRA "preempts state law tort claims," *ibid.*, and if so, whether FIFRA preempts "crop injury claims," Pet. 5-6. More generally, petitioners asserted a need to determine "the proper analysis to apply in determining which tort claims are preempted," Pet. at 19, and they identified five different potential tests, Pet. at 19-25. But petitioners specifically did not challenge the court of appeals' ruling that petitioners' claims are "label-related" in the sense that "a judgement against [respondent] would induce it to alter its product label." Pet. App. 15a. See Pet. 28-29. This Court accordingly should not entertain petitioners'

[14] Even if Section 136v(b) did not expressly preclude tort claims predicated on state common-law duties that are ostensibly "consistent with" FIFRA's misbranding prohibitions, such claims would be barred under principles of implied preemption, which are relevant even where Congress has provided an express preemption provision. See *Geier*, 529 U.S. at 869; *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 287-288 (1995). In this case, a State's imposition of common-law duties that are nominally similar to FIFRA's misbranding prohibition would nevertheless result, as a practical matter, in subjecting pesticide manufacturers to inconsistent labeling obligations that would stand as an obstacle to Congress's manifest goal of imposing a uniform body of federal labeling requirements. The claims would therefore be barred as a matter of implied preemption. See *Hines* v. *Davidowitz*, 312 U.S. 132, 142-143 (1963).

challenge to whether those particular claims are "label-related" at this stage of the proceedings. See *Board of Commissioners* v. *Umbehr*, 518 U.S. 668, 677 n.* (1996).[15]

The United States pointed out, at the petition stage, that the petition did not challenge this aspect of the court of appeals' ruling:

> In this Court, petitioners do not take issue with the court of appeals' conclusion that the state law claims at issue here would impose [requirements for labeling] insofar as they would compel respondents to change the label they obtained through the FIFRA approval process. See Pet. 28-29 (noting, without disputing, the court of appeals' characterization of "each of the claims as label-related and as 'inducing' the manufacturer to change its label or product").

U.S. Amicus Curiae Br. on Pet. 12. Petitioners did not contest that point in their supplemental response to the government's brief. See Pet. Supp. Br. 1-3.

The United States assumes that the Court granted review, in accordance with petitioners' request, to address the general standards that govern FIFRA preemption, and not to undertake the case-specific task of evaluating whether the pleadings in this particular case assert claims that fall outside of the scope of FIFRA preemption. The Court's resolution of the issues that petitioners properly raised in their petition—whether FIFRA preempts state-law tort

[15] Petitioners' articulation of the "question presented" in their petition does not identify the issue. Petitioners phrased the question presented as: "Which, if any, state law crop injury claims are preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-137." Pet. i. That question presents a challenge to the court of appeals' determination that petitioners' claims are "label-related" only in the sense that it presents a challenge to every aspect of the court of appeals' decision. Significantly, the body of the petition identifies the court of appeals' ruling on label-relatedness without calling it into question. Pet. 28-29.

claims that would impose labeling requirements and, if so, whether it nevertheless exempts product efficacy claims—would provide significant guidance for the lower courts. The Court should be reluctant to go further and resolve additional contentions that the specific claims at issue here "rest on legal duties that impose no alteration to an EPA-approved label." Pet. Br. 30; see *id.* at 40-50.[16]

[16] Petitioners suggest that the United States' amicus curiae brief in *Geye* supports their fact-bound challenges to the lower courts' determinations that their state-law claims are label-based. They read far too much into that brief. According to petitioners, "the U.S. acknowledges that strict liability claims should survive" (Pet. Br. 41), but the *Geye* brief in fact notes only that strict liability claims "need not" be label-based. U.S. Amicus Curiae Br. at 13, *American Cyanamid Co.* v. *Geye*, *supra* (No. 02-367). The brief does not state that Section 136v(b) would allow a strict liability claim in situations in which the claim "is functionally a disguised claim for failure to warn," as the court of appeals found in this case (Pet. App. 19a). See *Netland*, 284 F.3d at 899-901. Similarly, petitioners are mistaken in suggesting (Pet. Br. 45 n.32) that the United States endorsed their argument that Section 136v(b) "does not preempt" claims "stem[ming] from off-label statements." The passage from the United States' brief in *Geye* on which petitioners rely (U.S. Amicus Curiae Br. at 11-12, *American Cyanamid Co.* v. *Geye*, *supra* (No. 02-367) addressed alleged off-label statements that "substantially differed from" the relevant label. See *id.* at 6. By contrast, both courts below concluded that the alleged off-label statements at issue here did not "differ[] or stray[] in any material manner from the contents of the Strongarm label." Pet. App. 16a-17a; see *id.* at 25a.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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APPENDIX

Relevant Provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.*

7 U.S.C. 136. Definitions

* * * * *

(p) Label and labeling

(1) Label

The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

(2) Labeling

The term "labeling" means all labels and all other written, printed, or graphic matter—

(A) accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

(q) Misbranded

(1) A pesticide is misbranded if—

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

* * * * *

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment;

* * * * *

7 U.S.C. 136a. Registration of pesticides

(a) Requirement of registration

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

* * * * *

(c) Procedure for registration

* * * * *

(5) Approval of registration

The Administrator shall register a pesticide if the Administrator determines that, when considered with

any restrictions imposed under subsection (d) of this section—

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this subchapter;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 136v(c) of this title, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

* * * * *

7 U.S.C. 136j. Unlawful acts

(a) In general

(1) Except as provided by subsection (b) of this section, it shall be unlawful for any person in any State to distribute or sell to any person—

* * * * *

(E) any pesticide which is adulterated or misbranded; or

* * * * *

7 U.S.C. 136k. Stop sale, use, removal, and seizure

(a) Stop sale, etc., orders

Whenever any pesticide or device is found by the Administrator in any State and there is reason to believe on the basis of inspection or tests that such pesticide or device is in violation of any of the provisions of this subchapter, or that such pesticide or device has been or is intended to be distributed or sold in violation of any such provisions, or when the registration of the pesticide has been canceled by a final order or has been suspended, the Administrator may issue a written or printed "stop sale, use, or removal" order to any person who owns, controls, or has custody of such pesticide or device, and after receipt of such order no person shall sell, use, or remove the pesticide or device described in the order except in accordance with the provisions of the order.

* * * * *

7 U.S.C. 136*l*. Penalties

(a) Civil penalties

(1) In general

Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of this subchapter may be assessed a civil penalty by the Administrator of not more than $5,000 for each offense.

* * * * *

(b) Criminal penalties

(1) In general

(A) Any registrant, applicant for a registration, or producer who knowingly violates any provision of this subchapter shall be fined not more than $50,000 or imprisoned for not more than 1 year, or both.

(B) Any commercial applicator of a restricted use pesticide, or any other person not described in subparagraph (A) who distributes or sells pesticides or devices, who knowingly violates any provision of this subchapter shall be fined not more than $25,000 or imprisoned for not more than 1 year, or both.

* * * * *

7 U.S.C. §136v. Authority of States

(a) In general

A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

(b) Uniformity

Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

(c) Additional uses

(1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this subchapter and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator. Such registration shall be deemed registration under section 136a of this title for all purposes of this subchapter, but shall authorize distribution and use only within such State.

* * * * *

Supreme Court, U.S.
FILED
NOV 2 3 2004
OFFICE OF THE CLERK

No. 03-388

IN THE

Supreme Court of the United States

DENNIS BATES, *et al.*,

Petitioners,

v.

DOW AGROSCIENCES LLC,

Respondent.

On Writ of Certiorari to the
United States Court of Appeals for the Fifth Circuit

BRIEF FOR AMERICAN CHEMISTRY COUNCIL AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

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STATEMENT OF INTEREST*

The American Chemistry Council ("ACC") represents the leading companies engaged in the business of chemistry. Council members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. These products include pesticides and herbicides. The business of chemistry is a $460 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies invest more in research and development than any other business sector.

The ACC is very interested in the questions presented by this case. Members of the ACC include herbicide and pesticide manufacturers who are regulated by the Environmental Protection Agency and the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). Like Respondent, members of the ACC provide their pesticide and herbicide labels to the EPA for approval. Once the EPA approves the label, the warnings and instructions for these products are deemed adequate as a matter of law under FIFRA. As such, this Court's ruling on the preemption of Petitioners' claims by FIFRA against Respondent will have a large impact on the members of the ACC.

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*Pursuant to Rule 37.6, *amici* state that no counsel for any party authored any part of this brief. No person or entity, other than *amici*, made a monetary contribution toward the preparation or submission of this brief, which is filed with the parties' written blanket consent.

SUMMARY OF ARGUMENT

This amicus brief addresses a single issue raised by this proceeding, namely, whether the Fifth Circuit correctly held that Petitioners' "design defect" claims are properly preempted by FIFRA. The resolution of this issue is important to the ACC and its members, not only because they include manufacturers of pesticides and herbicides governed by FIFRA, but also because of the singular nature of chemical products and the way in which they may – and may not – be subject to tort liability.

In particular, it is the ACC's position that chemical products that conform to manufacturers' specifications can be found "unreasonably dangerous" only in the absence of adequate warnings and precautionary instructions. Because the manufacturers' warnings and instructions in this matter were adequate as a matter of law pursuant to federal approval, and because all other claims were preempted by FIFRA, the Fifth Circuit's judgment should be affirmed.

Chemicals are unique products — they "are what they are." Unlike machines or tools, chemical products are not merely assemblies of discrete components. Instead, chemicals are singular entities -- unique in themselves. Their elements and molecules are locked together by natural laws, not by nuts and bolts, and breaking chemical bonds does not merely "change" products – it actually transforms them into something completely different. Thus, it is impossible to "improve" a chemical product's "design" without producing a different product and vitiating the unique character of the original.

The nature of chemical products may be illustrated by referring to naturally occurring chemical compounds. For example, although carbon dioxide is not ordinarily toxic as

humans encounter it in everyday life, carbon monoxide is a deadly toxin. There is nothing "defective" in the "design" of carbon monoxide merely because it has one less oxygen molecule in its formula. Instead, what is needed is an adequate warning of its toxicity and adequate precautionary instructions to protect users from those dangers. When that information is provided, the dangers that are intrinsic to the compound's nature are not deemed "unreasonably dangerous."

The same principles apply to manufactured chemical products. Such materials may differ in their formulas and may have varying effects at varying doses and in varying applications. Yet merely because a manufactured chemical, such as a herbicide, has certain risks associated with its intended use does not mean that it is "defectively designed." Rather, the inherent risks associated with the compound's usage must be addressed by adequate warnings and instructions. In that way, the potential dangers associated with the chemical can be eliminated.

These principles are especially important in this action. Here, Petitioners contend that a herbicide, manufactured precisely according to the manufacturer's specifications, was "defectively designed" because it proved dangerous to crops when applied to soils of a particular character. Petitioners make this argument not because the product did not do what it was designed to do – namely, kill vegetation – but rather because the product did exactly what it was designed to do. To the extent that the product was unsuitable for use in certain soils, that "problem" does not arise from the product's "design," but rather from Petitioners' failure to appreciate the extent of the product's dangers and the precautions necessary to avoid them.

Petitioners' contentions are no more than disguised claims that Respondent failed to provide adequate warnings and instructions to alert Petitioners of certain dangers and the methods by which those dangers could be avoided. Although Petitioners argue that the design frustrated their "expectations" as consumers of the product, such expectations legitimately arise only when they are based upon information provided on the product's approved label. Because Petitioners' expectations are defined by the label, they also derive from the label's sufficiency as a source of necessary information. Accordingly, Petitioners' "defective design" claims are illusory. Further, because the labeled warnings and precautions are adequate as a matter of law under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"),[1] Petitioners are precluded from challenging their adequacy as a matter of law. Hence, the Fifth Circuit properly affirmed the district court's denial of relief to Petitioners.

ARGUMENT

SINCE PETITIONERS' CLAIMS CANNOT BE EVALUATED APART FROM THE EFFICACY OF RESPONDENT'S WARNINGS AND INSTRUCTIONS, THEIR ILLUSORY "DESIGN DEFECT" CLAIMS ARE PREEMPTED BY FIFRA.

Product liability claims are creatures of state law, and the standards for evaluating "design defect" claims vary

[1] *See* 7 U.S.C. 136 *et seq*. Federal control over pesticides began with the passage of The Insecticide Act in 1910. *See* H.R. Rep. No. 100-939, at 26 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3474, 3475. The passage of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") in 1947 replaced and repealed The Insecticide Act. *See id.*

from state to state.[2] It is not the purpose of this brief to analyze exhaustively whether Petitioners have stated a cause of action under any particular state's law. Rather, this brief is filed to address the arguments Petitioners raise to evade FIFRA's preemptive sweep.

Fundamentally, the resolution of this case hinges upon whether Petitioners can avoid FIFRA preemption by characterizing their claims as "defective design" causes of action, instead of as "failure to warn" claims that are plainly preempted. Petitioners argue that when a chemical product, such as a herbicide, is sold into the stream of commerce, consumers of that product have certain "expectations" regarding the product's efficacy and safety for its intended use. When a product fails to satisfy those "expectations" and causes harm, Petitioners assert that the product is "defectively designed" because its formulation is inconsistent with safe usage under foreseeable circumstances. Stated another way, Petitioners claim that the product's "risks" are allegedly outweighed by its "benefits."

In Petitioners' view, there are no meaningful distinctions between a "design defect" claim involving a chemical product and claims based upon defects in other types of products, such as machinery or tools. If a chemical product's formulation presents an unreasonable danger to persons or property in its foreseeable uses, the chemical is "defectively designed" and the manufacturer is subject to strict liability irrespective of the presence of adequate warnings and instructions. In this way, Petitioners seek to avoid FIFRA preemption by casting their claims as something other than claims based upon "failure to warn."

[2] *See generally,* Morton F. Daller, PRODUCT LIABILITY DESK REFERENCE, A FIFTY STATE COMPENDIUM (2004 ed.).

These arguments are fatally flawed because they ignore the confluence between the fundamental characteristics of chemical products and the necessity of considering the impact of adequate warnings in the context of "design defect" cases. Chemicals are unique products — they "are what they are." Unlike machines or tools, chemical products are not merely assemblies of discrete components. Instead, they are singular entities -- unique in themselves. Their elements and molecules are locked together by natural laws, not by nuts and bolts, and breaking chemical bonds does not merely "change" change products – it actually transforms them into something completely different. Thus, it is impossible to "change" or "improve" a chemical product's "design" without producing a different product and vitiating the unique character of the original. Accordingly, the adequacy of product warnings and instructions is the sole issue typically relevant in a chemical product liability case.

The nature of chemical products may be illustrated by referring to naturally occurring chemical compounds. For example, although carbon dioxide is not ordinarily toxic as humans encounter it in everyday life, carbon monoxide is a deadly toxin. Yet carbon monoxide is not "defectively designed" because it has one less oxygen molecule in its formula. Instead, what is needed is an adequate warning of its toxicity and adequate precautionary instructions to protect users from those dangers. When that information is provided, the dangers that are intrinsic to the compound's nature are not deemed "unreasonably dangerous."

The same principles apply to manufactured chemical products. Such materials may differ in their formulas and may have varying effects at varying doses and in varying applications. Yet merely because a manufactured chemical,

such as a herbicide, has certain risks associated with its intended use does not mean that it is "defectively designed." Rather, the inherent risks associated with the compound's usage must be addressed by adequate warnings and instructions. In that way, the potential dangers associated with the chemical can be eliminated – and liability for injuries resulting from its foreseeable uses can be avoided.

These principles are especially important in this action. Whether a state court proceeds under a "consumer expectations" or "risk/utility" analysis, or whether the question hinges on the availability of an alternative "safer design," the adequacy of warnings and instructions is an indispensable element of applying strict liability principles to chemical products. Under comment j of the Second Restatement of Torts,[3] considerations of the "design" of a product and its allegedly defective nature cannot be divorced from the warnings and instructions that accompany it. In fact, the thrust of comment j is that legally adequate warnings and instructions negate liability for allegedly defective designs as well as implied warranty claims.[4] Hence, "an adequate warning will make the product not unreasonably dangerous, thereby eliminating an essential

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[3] RESTATEMENT (SECOND) OF TORTS, § 402A, Cmt. j (1965).

[4] *See, e.g., Gauthier v. AMF, Inc.*, 788 F.2d 634, 635 (9th Cir. 1986)(Construing Montana law and holding "where adequate warnings are given, a product is neither defective nor unreasonably dangerous."). *See also Papike v. Tambrands, Inc.*, 107 F.3d 737, 744 (9th Cir. 1997) ("[T]he legally-adequate warnings . . . foreclosed Papike's claims for breach of warranty. The claim for punitive damages obviously fails as well."); *Temple v. Velcro USA, Inc.*, 148 Cal. App. 3d 1090, 1094 (1983) ("An adequate warning is a sufficient defense to a strict liability action. . . . If the warning was adequate it certainly . . . would also negate any negligence or willful misconduct.") (citations omitted).

element within the definition of strict liability."[5] Since FIFRA makes the legal adequacy of Respondent's warnings incontestable, Petitioners right to pursue a "design defect" claim under the Second Restatement is conclusively negated. Even if liability is not precluded directly, liability is

[5] *Jarrell v. Monsanto Co.*, 528 N.E.2d 1158, 1167 (Ind. Ct. App. 1988), *transfer denied*, 555 N.E.2d 453 (Ind. 1990) (original emphasis); *see also Ferguson v. F.R. Winkler GMBH & Co. KG*, 79 F.3d 1221, 1226 (D.C. Cir.), *cert. denied*, 519 U.S. 949 (1996) (citations omitted)("Much relevant precedent confirms that the presence of warnings may transform an otherwise unreasonably dangerous design, even as compared to other designs, into a safe one."). "When proper warnings are attached to such products, they are excepted from the Restatement's standard of defectiveness." *Cassisi v. Maytag Co.*, 396 So. 2d 1140, 1145 n.4 (Fla. Dist. Ct. App. 1981). *See also Bojorquez v. House of Toys, Inc.*, 62 Cal. App. 3d 930, 933 (1976) ("[T]he manufacturer of an unreasonably dangerous product may insulate himself from strict liability by adding a warning or giving directions on the container which keep the product from being deemed unreasonably dangerous."); *Tillman v. R.J. Reynolds Tobacco Co.*, 871 So.2d 28, 32 (Ala. 2003) ("[D]anger may be obviated by an adequate warning."); *Vitanza v. Upjohn Co.*, 778 A.2d 829, 836 (Conn. 2001) ("Proper warnings, however, may prevent a product from being unreasonably dangerous."); *Allen v. Long Mfg. NC, Inc.*, 322 S.C. 422, 505 S.E.2d 354, 357 (Ct. App. 1998) ("[A] seller may prevent a product from being unreasonably dangerous if the seller places an adequate warning on the product regarding its use."); *Hansen v. Sunnyside Prods., Inc.*, 55 Cal. App. 4th 1497, 1515 (1997) ("[C]onsideration of warnings . . . potentially permits the defendant to escape liability because of the low likelihood of harm."); *Cook v. Branick Mfg., Inc.*, 736 F.2d 1442, 1446 n.3 (11th Cir. 1984) ("[D]anger may be obviated by an adequate warning"); *Marshall v. Clark Equip. Co.*, 680 N.E.2d 1102, 1106 (Ind. Ct. App. 1997) ."), *transfer denied*, 698 N.E.2d 1186 (Ind. 1998)("[A] manufacturer may avoid liability by placing adequate warnings on a product even when there is evidence of a 'safer' alternative design; *Leachman v. Beech Aircraft Co.*, 694 F.2d 1301, 1306 (D.C. Cir. 1982) ("[T]he presence of warnings can cure the unreasonable danger."); *Shell Oil Co. v. Harrison*, 425 So. 2d 67 (Fla. Dist. Ct. App. 1982), *rev. denied*, 436 So. 2d 98 (Fla. 1983) (EPA-accepted product label for pesticide sold in bulk was adequate as a matter of law, thereby defeating claims for strict products liability and negligence).

nevertheless extinguished because "design" liability is inextricably intertwined with the adequacy of Respondent's warnings and instructions.

Although the Third Restatement retreats from the view that an adequate warning inevitably trumps a design defect claim,[6] it still acknowledges that "[r]easonable . . . instructions or warnings . . . play important roles in the production and distribution of reasonably safe products." [7] Further, comment f specifically states that "the warnings and instructions accompanying the product, and the nature and strength of consumer expectations regarding the product" are factors to be weighed in the "design defect" analysis.[8]

In cases involving chemical products, the issue of warnings is dominant because the Third Restatement insists upon proof of an alternative "safer design" as a prerequisite to a finding that the product's "design" is defective.[9] Since

[6] RESTATEMENT (THIRD) TORTS: PRODS. LIAB., § 2 cmt l (1998).

[7] *Id.*

[8] *Id.* Cmt. f.

[9] *Id.* at § 2(b)(A product "is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe."). Significantly, this requirement has been codified by statute under Texas law, the substantive law that governs the viability of Petitioners' claim here. *See* TEX. CIV. PRAC. & REM. CODE 82.005 (Vernon Supp. 2004). The Texas rule is consistent with the standard for finding "design defect" in the majority of other jurisdictions. *See* M. Stuart Madden, 1 PRODUCTS LIABILITY § 8.3, at 299 (2d ed. 1988) ("[T]he majority rule posits that plaintiff cannot establish a prima facie case of defective design without evidence of a technologically feasible, and practicable,

no "safer design" can be devised without transforming the chemical into a different compound, product liability claims involving chemical products can only be resolved by evaluating the adequacy of the manufacturers' warnings and precautionary instructions. Since warnings must be considered in any "design defect" calculus – regardless of which Restatement's standards are applied – all roads inexorably lead to FIFRA preemption.[10]

Here, Petitioners contend that a herbicide – manufactured precisely according to the manufacturer's specifications – was "defectively designed" because it proved dangerous to crops when applied to soils of a particular character. Petitioners make this argument not because the product did not do what it was designed to do – namely, kill vegetation – but rather because the product did exactly what it was designed to do. To the extent that the product was unsuitable for use in certain soils, that "problem" does not arise from the product's "design," but rather from Petitioners' failure to appreciate the extent of the product's dangers and the precautions necessary to avoid them.

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alternative to defendant's product that was available at the time of manufacture.").

[10] *See Akee v. Dow Chem. Co.*, 272 F. Supp. 2d 1112, 1132 (D. Haw. 2003) ("Plaintiffs are precluded from proving a strict liability design defect claim based on Hawaii's articulation of the risk-utility test, because such a claim is preempted by FIFRA."). *See also Oken v. Monsanto Co.*, 218 F. Supp. 2d 1361, 1366-67 (S.D. Fla. 2002)), *aff'd*, 371 F.3d 1312 (11th Cir. 2004)(FIFRA preempts Florida's risk/utility and consumer expectation tests for design defect). In the interest of brevity, the ACC does not provide an exhaustive analysis of the arguments supporting FIFRA preemption generally. The ACC presumes that the parties and other *amici* will address those arguments thoroughly in their own respective briefs.

As a result, Petitioners' "defective design" claims necessary depend upon a finding that the warning on the federally approved label was absent or inadequate. Since the "problem" alleged by Petitioners does not concern the efficacy of the product itself, but rather the lack of sufficient information to inform them of its alleged dangers, it necessarily derives from a "failure to warn" claim. Indeed, it seems clear that the "problem" can be "solved" merely by changing the label, which Respondent actually did when it secured approval for a supplemental label thereafter.[11]

If modifying the label is curative, as seems plain here, Petitioners' claims must be construed to challenge the sufficiency of the original label. Such a claim has nothing to do with the product's "design" – and everything to do with the alleged failure of the label to provide enough information to prevent their injuries. Although the line between mislabeling and a claim for a defective product has been described as "razor thin," the resolution turns upon "whether one could reasonably foresee that the manufacturer, in seeking to avoid liability for the error, would choose to alter the product or the label."[12] Of course, such an alteration actually occurred in this matter, illustrating Petitioners' error

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[11] Respondent successfully petitioned the EPA for permission to issue a supplemental label for use in 2001. J.A. 179. The supplemental label provided more specific instructions for soils with pH levels of 7.2 or higher, stating: "Do not apply Strongarm to soils with a pH of 7.2 or greater." J.A. 181.

[12] *Worm v. American Cyanamid Co.*, 5 F.3d 744, 747 (4th Cir. 1993); *see also Andrus v. AgrEvo USA Co.*, 178 F.3d 395, 399 (5th Cir. 1999)(holding plaintiffs' state law claims were preempted because success on their claims would have necessarily had the effect of "imposing additional labeling standards").

in insisting that their claims are legitimately true "defective design."

However creative Petitioners' contentions may appear, they are no more than a disguised claim that Respondent failed to provide adequate warnings and instructions to alert Petitioners of certain dangers and the methods by which those dangers could be avoided. Although Petitioners argue that the design frustrated their "expectations" as consumers of the product, such expectations legitimately arise only when they are based upon information provided on the product's approved label. Because Petitioners' expectations are defined by the label, they also derive from the label's sufficiency as a source of necessary information.

FIFRA preempts state laws that either directly or indirectly impose different labeling requirements.[13] FIFRA's express preemption clause preempts claims if they would induce the pesticide manufacturer to alter its product label, irrespective of the particular cause of action asserted.[14] Petitioners cannot legitimately argue that their "consumer expectations" were frustrated by the herbicide's "defective" formula in this case. Legitimate "expectations" can only be defined by the product's label, not by vague notions conjured in hindsight after a purchase is concluded. When a warning label has been approved by the EPA, it would be "anomalous to hold that a consumer is entitled to expect a product to

[13] *MacDonald v. Monsanto*, 27 F.3d 1021, 1025 (5th Cir. 1994).

[14] *Worm v. American Cyanamid Co.*, 5 F.3d 744, 747 (4th Cir. 1993); *see also Andrus v. AgrEvo USA Co.*, 178 F.3d 395, 399 (5th Cir. 1999)(holding plaintiffs' state law claims were preempted because success on their claims would have necessarily had the effect of "imposing additional labeling standards").

perform more safely than government-mandated warnings indicate."[15] For that reason, FIFRA preempts "design defect" claims based upon allegedly frustrated "consumer expectations."[16] Any other holding "would represent an

[15] *Lescs v. William R. Hughes, Inc. ("Lescs II")*, 168 F.3d 482, 1999 WL 12913, at *12 (4th Cir. 1999) (citations and internal quotation marks omitted). *See also Oken v. Monsanto Co.*, 218 F. Supp. 2d 1361, 1366-67 (S.D. Fla. 2002) ("The objective expectation of the public regarding the dangerousness of a product necessarily involves consideration of the warning given to the public. Therefore, such design defect claims as Plaintiff brings under Florida law as to Dursban, a product regulated under FIFRA by the federal government, are preempted."); *accord, Ruiz-Guzman v. Amvac Chem. Corp.*, 243 F.3d 549, 2000 WL 1763212, at *1 (9th Cir. 2000) ("We agree with the district court that FIFRA preempts Washington's consumer expectation test." (citing *Papike*)); *Eriksen v. Mobay Corp.*, 41 P.3d 488, 494-95 (Wash. Ct. App. 2002) (FIFRA preempts Washington's consumer expectation test for design defect); *Dow Chem. Co. v. Ebling*, 723 N.E.2d 881, 910-922 (Ind. Ct. App. 2000) (Sharpnack, C.J., dissenting in part), *aff'd in part, rev'd in part*, 753 N.E.2d 633 (Ind. 2001) ("State tort law that permits recovery based on consumer expectations different from those that could be supported by the information required to be set forth on labels by FIFRA is in effect no different than state tort law that allows recovery for failure to make warnings different from or in addition to those set forth on the label."). *But see Arnold v. Dow Chem. Co.*, 110 Cal. Rptr. 2d 722, 743-45 (Cal. Ct. App. 2001).

[16] *Papike v. Tambrands, Inc.*, 107 F.3d 737, 743 (9th Cir. 1997) ("[Defendant's] warnings met the federal requirements and [plaintiff's] design defect claim therefore fails the "consumer expectation" test. To rule otherwise would allow the anomalous circumstance that a consumer is entitled to expect a product to perform more safely than its government-mandated warnings indicate."); *Haddix v. Playtex Family Prods. Corp.*, 138 F.3d 681, 686 (7th Cir. 1998) (same); *Akee v. Dow Chem. Co.*, 272 F. Supp. 2d 1112, 1132 (D. Haw. 2003); *Lescs v. Dow Chem. Co.* ("*Lescs I*"), 976 F. Supp. 393, 399 (W.D. Va. 1997), *aff'd sub nom. Lescs II*, 168 F.3d 482 (4th Cir. 1999), *cert. denied*, 528 U.S. 1119 (2000)("Plaintiff cannot proceed under a consumer expectations theory to show defective design because such a claim is preempted by FIFRA. . . . Like the product in *Papike*, Dursban is regulated by a federal legislative scheme which broadly preempts state claims based on federally approved

unwarranted end-run around federal preemption." [17] Accordingly, Petitioners' illusory "defective design" are preempted by FIFRA.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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labeling. For this court to allow a claim of defective design based on consumer expectations would represent an unwarranted end-run around federal preemption. . . . [T]he court is of the opinion that this aspect of Plaintiff's claim of unreasonably dangerous design is preempted by FIFRA."); *Reece v. Good Samaritan Hosp.*, 953 P.2d 117, 123 (Wash. Ct. App. 1998) (same).

[17] *Lescs I*, 976 F. Supp. at 399.

(9)

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DENNIS BATES, ET AL.,

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Respondent.

On Writ Of Certiorari to the United States Courts of Appeals for the Fifth Circuit

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No. 03-88

IN THE

Supreme Court of the United States

DENNIS BATES, ET AL.,

Petitioners,

v.

DOW AGROSCIENCES LLC,

Respondent.

AMICUS CURIAE BRIEF OF THE ASSOCIATION OF TRIAL LAWYERS OF AMERICA IN SUPPORT OF PETITIONERS

IDENTITY AND INTEREST OF *AMICUS CURIAE*

The Association of Trial Lawyers of America ["ATLA"] respectfully submits this brief as amicus curiae. The parties have filed letters of consent to the filing of amicus briefs with this Court.[1]

ATLA is a voluntary national bar association whose approximately 50,000 trial lawyer members primarily represent individual plaintiffs in civil actions brought under state tort law.

Frequently our members have represented farmers whose crops have been damaged or destroyed by pesticides that were either untested,

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[1] Pursuant to Rule 37.6, Amicus discloses that no counsel for a party authored any part of this brief, nor did any person or entity other than Amicus Curiae, its members, or its counsel make a monetary contribution to the preparation or submission of this brief.

badly formulated, defectively produced, or falsely marketed.

Because pesticide labels are regulated by FIFRA, there are, to our knowledge, only two reported cases (both state supreme court decisions) over the past 20 years where farmers' state crop damage claims have survived FIFRA's preemption clause. As a result, farmers claiming crop damages from harmful pesticides have been left without any remedy for the wrong done to them.

In ATLA's view, the legislative history of the Act since 1978 reveals that Congress did not intend FIFRA to preempt state common law tort actions for crop damage.

How do you explain to an American farmer that he has no remedy at law when his crops have been damaged or destroyed by an unsafe pesticide that the manufacturer claimed was safe? There is no reasonably acceptable explanation.

SUMMARY OF ARGUMENT

1. This case is an opportunity for the Court to correct two decades of injustice borne by farmers across America. Congress enacted the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to address safety and environmental concerns posed by such products. The Act precluded states from imposing requirements "in addition to or different from" the federal requirements under the Act. In 1978, Congress amended FIFRA to end EPA review of the efficacy of registered products. That amendment and its impact on the scope of FIFRA's preemptive scope, have been largely ignored by federal courts that have held farmers' state law claims for crop damage to be

preempted. Closer examination supports Petitioners' argument in this case that such claims are not preempted by FIFRA.

Congress enacted the Federal Pesticide Act of 1978 amending FIFRA, 7 U.S.C.A. § 136a (c)(5), authorizing the EPA to waive the requirement that producers submit data showing the efficacy of their products. Congress intended both to ease the regulatory burden on the industry and to leave the efficacy of agricultural pesticides to the judgment of the marketplace. The EPA subsequently adopted such a waiver by regulation, taking the federal government out of the business of regulating the efficacy of pesticides, focusing instead on protection of people and the environment.

These actions by Congress and the EPA removed property damage claims from the scope of FIFRA preemption. They draw a clear distinction between state claims for personal injury or environmental damage and those for property damage. The former are label-based because the label process requires review and approval of data relating to hazards to humans and the environment. Property damage claims are no longer label-based because the EPA in the label approval process no longer reviews the effect of a pesticide on crops. Petitioners' crop damage claims in this case are precisely the type of claim that Congress left to state regulation and the marketplace, including state tort law. This crucial distinction, however, has gone largely unnoticed by federal courts presented with such claims.

2. This Court has held that the general tort duties not to make false statements or misrepresentations in marketing materials are not requirements in

addition to or different from specific federal requirements for purposes of express preemption. FIFRA's preemption of state "requirements for labeling or packaging" does not encompass the general tort duties against false statement and misrepresentation. Nor are such tort duties displaced where they are the same as or parallel to federal requirements, so long as they do not conflict with those federal requirements.

In addition, as Congress made plain in the text of the preemption provision, FIFRA preempts only those state requirements that are "in addition to or different from those required under the Act." Because EPA has waived efficacy as a labeling requirement, there is no relevant federal requirement that would displace state law. Nor does it appear that Congress intended the EPA to regulate statements in producers' marketing materials, as distinguished from label contents.

To hold otherwise would grant producers complete immunity for wrongful crop damage. To the extent that Congress intended to benefit producers by amending FIFRA, Congress did so by easing the burden of regulation. Congress did not intend to deprive users of all legal redress.

3. The court below unaccountably ignored this Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). FIFRA's express preemption provision is very similar to the provision in that case. Additionally, the *Medtronic* Court refused to give preemptive effect to FDA approval of a product that had been exempted from the agency's usual rigorous testing and review. This Court should hold in this case, as in *Medtronic*, that Petitioners' claims fall outside the scope of preemption created by Congress.

ARGUMENT

I. THE FIFRA EXPRESS PREEMPTION CLAUSE DOES NOT APPLY TO CROP DAMAGE CLAIMS.

A. Congress Amended FIFRA In 1978 To End EPA Regulation of Product Efficacy, Removing Crop Damage Claims From The Scope of FIFRA Preemption.

Congress enacted the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.* to address safety and environmental concerns posed by such products. *Wisconsin Public Intervenor v. Mortier,* 501 U.S. 597, 601 (1999). The Act preserved limited authority of the states to regulate such products, but precluded state requirements "in addition to or different from" the federal requirements.[2]

On July 6, 1977, the United States Senate reported its intent to amend FIFRA to allow the EPA to waive the requirement that producers submit data on the effect of agricultural pesticides upon crops,

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[2] 7 U.S.C § 136v provides:

(a) In General

A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

(b) Uniformity

Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

The report recognized that the EPA's primary function was to protect humans and the environment and that all of EPA's resources should be directed to that end. It also noted that existing efficacy data was of questionable value and that manufacturers were unlikely to register non-efficacious products. In addition, it would reduce the regulatory burden upon manufacturers and leave efficacy of agricultural pesticides to those better able to judge such as producers, USDA, and the marketplace of users. S. Rep. No. 95-334, at. 2, 9, 19, 20, 28, and 73 (1977).

On September 30, 1978, Congress passed the Federal Pesticide Act of 1978 amending FIFRA. 7 U.S.C.A. 136a (c)(5) and authorizing the EPA to waive the efficacy requirement. Eight months later, on May 11, 1979, the EPA acted on that authority, restating the Congressional intent and proposing a regulatory waiver:

> The agency's viewpoint concerning waiver of efficacy data requirements is in line with the general belief among persons in the pesticide industry, the U. S. Department of Agriculture and the agricultural community that the efficacy of agricultural pesticides can be effectively regulated by the marketplace (in conjunction with extension services and university research personnel).
>
> The decision to pursue efficacy waiver as an agency policy stems from a need to reduce the amount of resources devoted to reviewing product performance so that additional effort could be devoted to the evaluation of health and safety data, and from a desire to reduce regulatory burdens in the pesticide registration process...therefore, commitment of the resources needed to fully evaluate this data for purposes of registration was determined to be less than the ideal use of limited resources for pesticide regulation.

44 Fed. Reg. 27932, 27938 (May 11, 1979).

On November 3, 1980, the EPA returned to the waiver question by issuing guidelines for pesticide assessment. 45 Fed. Reg. 72948 (Nov. 3, 1980). This rule more expansively stated that efficacy requirements for all pesticides are waived unless there is a direct impact on public health and that the industry as well as the United States government believes that the marketplace effectively regulates the efficacy of pesticides. 45 Fed. Reg. 72951. It also waived submission of phytotoxicity data where efficacy data is no longer required and clearly stated that consumer fraud claims would be left to state regulation, which the agency would simply monitor:

> The pesticide industry was generally supportive of the concept of efficacy waiver. . . . EPA . . . will monitor the impacts of the efficacy waiver policy to determine if . . . *consumer fraud* is effectively reported and curtailed through existing market institutions including state regulation processes and the USDA and the extension service, farmers associations and the marketplace.
>
> The agency expects that all registrants will perform the tasks necessary to assure themselves that the products the (sic) market will perform their intended functions when applied in accordance with label directions and commonly accepted pest control practices. The agency must rely upon the integrity of the industry, the soundness of extension service recommendations and the good judgment of

> pesticide users to insure that abuses seldom occur.

45 Fed. Reg. 72948, 72951 (Nov. 3, 1980) (emphasis added).

In EPA's view, Congress did not intend the waiver to confer immunity from state tort liability on producers. To the contrary, the EPA clearly anticipated that state tort suits would provide the incentive for producers to ensure the efficacy of their products. As the EPA stated in its proposed rule to waive the requirement for submission of efficacy data,

> The Agency expects and believes that registrants will ensure that their products are efficacious when used in accordance with label directions and commonly accepted practice because FIFRA at section 3(c)(5)(A) requires it and *because pesticide producers are aware that they are potentially subject to damage suits* by the user community if their products prove ineffective in actual use.

47 Fed. Reg. 40659, 40661 (Sept. 15, 1982) (emphasis added).

Indeed, in proposing that Code of Federal Regulations, Title 40, be amended to add a new section 158 incorporating its waiver of performance data review, the EPA specifically stated:

> This change is based on the Agency's perception that registrants routinely conduct extensive testing to assess the phytotoxicity of their products on their own, either to assess efficacy (in the case of herbicides), and/or to develop appropriate use instructions and precautionary labeling in order *to ensure that their products do not impart any detrimental effects (particularly*

> *on crops, ornamentals and other desirable plants) for which they could be liable.*

Pesticides Registration; Proposed Data Requirements, 47 Fed. Reg. 53192, 53196. (Nov. 24, 1982) (emphasis added).

The regulation was adopted and states, in pertinent part:

> The agency has waived all requirements to submit efficacy data unless the pesticide product...poses a threat to human health. . . However, each registrant must insure through testing that his products are efficacious when used in label directions and commonly accepted pest control practices.

40 C.F.R. § 158.640(b)(1).

Prior to the waiver, FIFRA required submission by a registered producer to the EPA of all testing data for a product's effects when used as intended and expressly preempted state claims once the EPA completed the label approval process. Claims were characterized as label-based, and therefore expressly preempted, when they related to the data that had been reviewed and approved by the EPA in a label approval process.

The effect of these congressional and EPA actions was to carve a small niche out of FIFRA's preemptive scope. Claims for crop damage caused by a registered product were no longer label-based because no testing data on the effect of the product on crops was submitted to or reviewed by the EPA in the FIFRA label approval process. Such claims could not, therefore, result in label requirements "in addition to or different" from those required by the Act. The benefits to the industry in not having to

submit efficacy data to the EPA was a trade-off for loss of preemption in crop damage cases.

Congress and the EPA have effectively drawn a clear distinction, for preemption purposes, between state claims made for personal injury or environmental damage and those made for property damage. The former are prima facie label-based because the label process requires review and approval of data relating to health of humans and the environment. Property damage claims are no longer label-based following the end of EPA review of the product's effects on crops. Stated differently, if efficacy is not a requirement of the EPA in its approval process, and a state tort claim is predicated only on the efficacy of the product, then the state claim is not "a requirement for labeling. . . in addition to or different from those required under this subchapter." 7 U.S.C.A. § 136v(b). State tort claims based upon damage caused by a pesticide's efficacy simply do not intrude upon or conflict with the existing federal requirements.

Petitioners' claims for defective design and negligent manufacture arise directly from the effect of Dow's herbicide, Strongarm, on crops when used as intended, and do not involve personal injuries or environmental damage. They are precisely the type of claims that Congress left to state regulation and the marketplace, including state common law tort duties.

B. Federal Courts Have Ignored the 1978 Amendment In Holding Crop Damage Claims Preempted By FIFRA.

Unfortunately, impact of Congress's action went largely unnoticed for 20 years by courts addressing preemption questions. During that time,

no less than seven U.S. Circuit Courts had well-established precedents holding crop damage claims preempted. None of those courts was apparently aware of the 1978 amendment, which was never raised or discussed in their decisions.

The EPA raised its voice in an *amicus curiae* brief filed in the California Supreme Court, explaining the reality of its process under FIFRA and that preemption of crop damage claims was not consistent with that reality. *See* U.S. Amicus Br., *Etcheverry v. TRI-AG Serv. Inc.*, No. S072524 (Cal. filed Mar. 1999). The court nevertheless held plaintiff's claims preempted, making a classic distinction without a difference by distinguishing phytotoxicity from crop damage. *Etcheverry v. Tri-Ag Service, Inc.*, 93 Cal. Rptr. 2d 36, 993 P.2d. 366 (2000). Phytotoxicity is defined in Webster's Dictionary as "poisonous to plants" and is specifically characterized by the EPA in its regulations as part of the efficacy domain. 45 Fed. Reg. 72948, 72950-51 (Nov 3, 1980).

In 2002, the Texas Supreme Court, in *American Cyanamid Co. v. Geye*, 79 S.W. 3d. 21 (Tex. 2002), properly interpreted Congressional intent and the EPA regulations, and held that the claims of peanut farmers whose crops were damaged by defendant's herbicide were not preempted under FIFRA.

The Fifth Circuit Court in this case affirmed a declaratory judgment grant of preemption by the trial court by distinguishing between express preemption and an "ordinary conflict preemption" case, stating that *American Cyanamid* was the latter, while this case is the former. *Dow Agrosciences LLC v. Bates,* 332 F.3d 323, 330 & n.13

(5th Cir. 2003). This characterization is clearly erroneous. As the Texas court itself stated: "This is an express preemption case," quoting FIFRA's express preemption provision, 7 U.S.C. § 136v(b), as the basis for its decision. *American Cyanamid*, 79 S.W. 3d. at 24.

Thus, the intent of Congress was an intentional transference of claims for a pesticide's efficacy from the EPA to a far superior arbiter of such claims – the marketplace. It took the federal government out of the business of warranting a product's efficacy when used and returned to its original purpose of protecting people and the environment. These new contours of the Act were supposed to return harmony between its original intent and the subsequently expected results. They did not. The federal circuits remained largely unaware of this development and its removal of crop damage claims from the scope of FIFRA's preemption. This case presents this Court with the opportunity to correct this glaring failure of justice.

II. FIFRA'S EXPRESS PREEMPTION CLAUSE DOES NOT PREEMPT STATE CONSUMER FRAUD AND DECEPTIVE TRADE PRACTICES ACTIONS.

A. State Actions For False Representations Are The Only Enforcement Tool Of The FIFRA Requirement Prohibiting False Statements Of A Product's Effectiveness And The Sole Remedy Available To Those Injured By The Falsity.

Petitioners' state law causes of action include not only claims of defective design and negligent

manufacture, but also claims based on false statements and misrepresentation. These claims too, ATLA submits, are not preempted under FIFRA.

7 U.S.C. § 136v(b) prohibits states from imposing requirements for labeling that are "in addition to or different from" those required under the Act. One question, then, is whether claims alleging crop damage due to false or misleading statements in producers' marketing materials are preempted as imposing requirements in addition to or different from the federal requirements.

This Court answered that question in its decisions in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

In *Cipollone*, this Court dealt with the Federal Cigarette Labeling & Advertising Act, which, unlike FIFRA, was narrowly directed solely towards the advertising of cigarettes. The plurality opinion by Justice Stevens stated, "The predicate of this claim is a state-law duty not to make false statements of material fact or to conceal such facts." 505 U.S. at 528.

Is that state-law duty the sort that imposes a requirement that results in preemption? The Court's response was that "Congress offered no sign that it wished to insulate cigarette manufacturers from longstanding rules governing fraud." *Id.* at 529. Rather, "State-law prohibitions on false statements of material fact do not create diverse, non-uniform and confusing standards." *Id.* The Court explained that, "[u]nlike state-law obligations concerning the warning necessary to render a product 'reasonably

safe,' state-law proscriptions on intentional fraud rely only on a single uniform standard: falsity." *Id.*

"Accordingly," the Court concluded, "petitioner's claim based on allegedly fraudulent statements made in respondents' advertisements is not preempted." *Id.*[3]

The opinion of Justice Blackman, concurring and dissenting in part, joined in by Justice Kennedy and Justice Souter, characterized the plurality holding as follows: "The plurality states that fraudulent misrepresentation claims (at least those involving false statements of material fact in advertisements) are 'predicated not on a duty based on smoking and health' but rather on a more general obligation – the duty not to deceive,' and therefore are not pre-empted." *Id.* at. 543.

In *Medtronic*, after a thorough review of the legislative history of the Medical Device Amendments of 1976, this Court found nothing to indicate that Congress "intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective products." 518 U.S. at 491.

The Court made clear the express preemption provision there did not deny a state "the right to provide a traditional damages remedy for violations of common-law duties when those duties *parallel* federal requirements." *Id.* at 495. Nor did it preempt "state or local requirements that are *equal to, or*

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3 The Supreme Court of Wisconsin came to the same conclusion in interpreting FIFRA. *Gorton v. American Cyanamid*, 194 Wis. 2d 203 (1995), 533 N.W. 2d 746 (1995).

substantially identical to, requirements imposed by or under the act." *Id.* at 496-97. (Emphasis added).

The plurality concluded that state law actions would be preempted "only where a particular state requirement threatens to interfere with a specific federal interest." *Id.* at 500.

On this issue there was agreement among all Justices. The opinion authored by Justice O'Connor, concurring in part and dissenting in part, joined in by the Chief Justice, Justice Scalia and Justice Thomas, was in full agreement that state tort actions which parallel requirements of the Act are not preempted. Justice O'Connor stated initially that "state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would *differ* from those imposed by the FDCA." *Id.* at 509 (emphasis added). Justice O'Connor continued:

> Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is "different from, or in addition to" requirements under federal law. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. Section 360k does not preclude States from imposing different or additional remedies, but only different or additional requirements.

Id. at 513.

The Justices therefore would unanimously agree that on the narrow issue that when a state misrepresentation action is filed against a manufacturer for making false statements in its marketing materials, and where the Act contains a

similar prohibition against false and misleading statements, then the state law action is not a requirement different from or in addition to the federal requirement. It merely provides a different remedy.

While *Medtronic* did not deal with FIFRA but with the MDA, the language of the preemption clauses is the same. Indeed, the FDA promulgated a regulation stating that the preemption provision in the FDCA "does not preempt state or local requirements that are equal to or substantially identical to requirements imposed by or under the Act." *Medtronic*, 518 U.S. at 496-97, quoting 21 C.F.R. § 808.1(d)(2) (1995).

FIFRA does specifically prohibit false and misleading statements. The regulations for the labeling requirements prohibit:

> (i) a false or misleading statement concerning the composition of the product;
>
> (ii) a false or misleading statement concerning the *effectiveness of the product* as a pesticide or device;
>
> (iii) a false or misleading statement about the value of the product for purposes other than a pesticide or device;
>
> (iv) a false or misleading comparison with other pesticides or devices; . . .
>
> (vii) a true statement used in such a way as to give a false or misleading impression to the purchaser; . . .
>
> (ix) claims as to the safety of the pesticide or its ingredients, including statements such as "safe", "non-poisonous", "non-injurious", "harmless" or "non-toxic to humans and pets" with or without such qualifying phrase as "when used as directed."

See 40 C.F.R. § 156.10 (emphasis added)

The Petitioners in this case raised state law tort claims of strict liability, breach of warranty, fraud, and violations of the Texas Deceptive Trade Practices Act (TDTPA). These allegations make up a partial list of common and oft-repeated allegations one would expect in common-law tort claims against a manufacturer who has made allegedly false claims about its product in its off-label marketing. *See Gorton v. American Cyanamid,* 194 Wis. 2d 203, 533 N.W.2d 746 (1995). ATLA's members have pioneered consumer protection litigation by enforcing state consumer protection laws through filing state civil tort actions based on the foregoing classic allegations.

In this case, Petitioners allege violations of the Texas Deceptive Trade Practices Act, which makes unlawful "representing that goods or services are of a particular standard, quality or grade or that goods are of a particular style or model, if they are of another." Tex. Bus. & Comm. Code § 17.46(b)(7). A violation of the Act occurs when a manufacturer misrepresents the standard or quality of its product in its marketing materials. The Texas Act is not unlike the consumer protection acts that most states have adopted, all of which prohibit falsity in advertising or sales. The same kinds of misrepresentations would also constitute a violation of FIFRA based on the aforementioned regulations 40 C.F.R. § 156.10(a)(5) ii and ix.

Because the tort claim of misrepresentation is a claim parallel to the FIFRA requirement, it is, under both *Cipollone* and *Medtronic*, not "in addition

to or different from" the FIFRA requirement, and thus not subject to preemption. The remedy may differ, but the requirement remains the same.

Starting with the principle that state claims based on allegedly false statements made in a manufacturer's advertisements are not preempted when those claims do not interfere with a federal requirement, and following the reasoning in *Cipollone* and *Medtronic* that state actions parallel or equal to or substantially identical to federal requirements are not preempted, and recognizing that FIFRA requirements prohibit false or misleading statements about the pesticide's effectiveness or safety, one can only conclude that state tort actions for false statements in marketing materials are not preempted under FIFRA.

B. State Court Actions That Give Rise To A Requirement In The Absence Of Any Federal Requirement Are Not Preempted.

There is an additional reason to conclude from *Cipollone* and *Medtronic* that false statements about a pesticide's effectiveness brought in state Court tort actions are not preempted by FIFRA: There cannot be preemption where there is no requirement under the Act.

As discussed above, FIFRA long ago waived efficacy as a labeling requirement, shortly after Congress authorized such a waiver. Since efficacy deals with how a product works when it is used as intended, any false or misleading statements relating to a pesticide's efficacy could not be preempted and would be subject only to remedial actions under state law in the absence of any federal requirement or federal remedy. Congress made clear

in 7 U.S.C. § 136v(a), quoted at n.2, *supra*, that it did not intend that manufacturers escape entirely from accountability under both federal and state law. Rather, Congress underscored that the States retain their historic authority to regulate pesticides and similar products, provided only that they "not permit any sale or use prohibited by this subchapter." *Id.*

Congress intended an orderly federal-state cooperation in regulating pesticides and other potentially harmful products under FIFRA. *See Mortier*, *supra,* at 501 U.S. 601-02. Under the statute's plain language, in the absence of a FIFRA requirement regulating how a product works to aid or protect a crop or a plant, false or misleading statements as to the product's effectiveness or safety fall under state regulation. Preemption of state requirements, in the absence of a federal requirement, would grant unintended immunity to all manufacturer's statements regarding the effectiveness of its products and would leave aggrieved parties without any remedy.

It was not the intent of Congress to create such an immunity for harm to crops when it amended FIFRA to end the regulation of product efficacy by EPA in 1978. Rather, its motivation was similar to that underlying the Medical Device Amendments of 1976: "To the extent that Congress was concerned about protecting the industry, that intent was manifested primarily through fewer substantive requirements under the Act, not the pre-emption provision." *Medtronic, supra,* 518 U.S. at 490. Significantly, the industry favored the waiver of efficacy as a requirement because it lessened the regulatory burden. S. Rep. No. 95-334, at 20 (1977).

Under the similar preemption provision in the Medical Device Amendments, "a state law will be pre-empted only to the extent that the FDA has promulgated a relevant federal 'requirement.'" *Medtronic*, 518 U.S. at 496. This Court addressed a similar argument in *Freightliner Corp. v. Myrick,* 514 U.S. 280, 286 (1995). Where Congress did not intend to occupy the field of motor vehicle regulation, but rather preempted any state safety standard "which is not identical to the Federal standard," this Court held that in the absence of a federal standard, "States remain free to 'establish, or to continue in effect,' their own safety standards." *Id.* at 286.

In this case, the waiver of the efficacy requirement left no basis to preempt false claims made by a manufacturer about its product's effectiveness, because the waiver removed it from the regulatory scheme by waiving any federal requirements for efficacy with which a state cause of action could conflict.

Making a false statement about a product's effectiveness which violates state court tort law is not preempted because such statements are both not permitted by and not regulated by FIFRA. Ironically, because falsity in marketing is prohibited by FIFRA but a product's efficacy is not regulated by FIFRA, state consumer protection actions are the sole remedy for damages from ineffective products as well as being the sole enforcement tool available for violation of the federal prohibition against falsity.

Marketing materials are a totally different animal than labels, both in their purpose and content. Marketing materials are not about how to use the pesticide but why the customer should use a specific one. The brochure or publication's purpose is

to convince the end user to buy its product instead of someone else's.

Thus, how to use a pesticide (the label) is as different from why to buy a pesticide (the brochure) as the motivation to protect man and his environment is from the motivation to make a profit on a sale.

We could find no specific authority in FIFRA for the EPA to engage in a review of a manufacturer's marketing claims or selling techniques, nor is it reasonable to assume that Congress would assign such authority to an essentially scientific governmental agency, especially since consumer protection has traditionally been a domain occupied by the states.

The only specific reference we could find appears in the EPA's "Proposed Guidelines for Registering Pesticides in the United States," promulgated in 1980. After an in-depth discussion of why EPA has waived efficacy testing as a requirement for labeling approval, the agency dealt with consumer fraud almost in a passing fashion. In a brief reference, the EPA made clear its view that "consumer fraud is effectively reported and curtailed through existing market institutions, including state regulation processes, USDA and the extension service, farmers associations and the marketplace." 45 Fed. Reg. 72948, 72951 (Nov. 3, 1980). The guidelines also, however, categorically state that the EPA expects that "all registrants will perform the tasks necessary to assure themselves that the products they market will perform their intended functions" and that the EPA "must rely upon the integrity of the industry." *Id.*

Therefore, causes of action against a manufacturer for consumer fraud or deceptive trade practices could not reasonably have been intended to be preempted by Congress. In the absence of EPA regulation to prevent consumer fraud in marketing materials, Congress intended the states to play their role in cooperative regulation of registered products.

III. CROP DAMAGE CLAIMS WOULD NOT BE PREEMPTED UNDER THE MEDTRONIC ANALYSIS

A. The Preemption Clauses Are Markedly Similar

The court below unaccountably ignored this Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). This Court there examined the express preemption clause under the MDA, which is remarkably similar to the preemption clause under FIFRA. With Congressional intent being this Court's primary concern, the preemption analysis began with two main principles in the forefront. The first was that there is a long-standing presumption against preemption and that the police powers of the state are not to be superceded by a federal act unless it was the clear and manifest purpose of Congress. 518 U.S. at 485. The second principle was that "the purpose of Congress is the ultimate touchstone" in every preemption case. *Id.* at 486.

The analysis of any preemption clause therefore rests primarily on a fair understanding of Congressional purpose as "discerned from the language of the preemption statute and the statutory framework surrounding it." *Id.* at 485-86. This Court first examined the language of the preemption clause, which reads:

> State and local requirements respecting devices
>
> (a) General rule
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement–
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k.

While examining the above language, this Court found the use of the word "requirement" to be significant to its analysis, noting that if Congress intended to preclude all common-law causes of action, "it chose a singularly odd word with which to do it. The statute would have achieved an identical result, for instance, if it had precluded any 'remedy' under state law relating to medical devices." 528 U.S. at 488.

This Court further explained:

> "Requirement" appears to presume that the State is imposing a specific duty upon the manufacturer, and although we have on prior occasions concluded that a statute pre-empting certain state "requirements" could also pre-empt common-law damages claims, [citing *Cipollone*] that statute did not sweep nearly as broadly as Medtronic would have us believe that this statute does."

Id. at 488.

The Court then distinguished the Medical Device Amendments from the statute in *Cipollone*, holding that the territory under the preemptive clause in *Cipollone* was exclusively occupied by federal law as defined in the text of the statute and the word "requirement" is used throughout the entire statute, unlike the MDA, where the word "requirement" is linked "with language suggesting that its focus is device-specific enactments," and "not the application of general rules of common law by judges and juries." *Id.* at 489.

If the *Medtronic* analysis is applied to the preemption clause under FIFRA, it is clear that FIFRA's preemption authority would not extend to crop damage claims.

P.R. Notice 96-4 sets forth the EPA's policy that approval of pesticide labels no longer reflects any determination on the part of the EPA that the pesticide will be efficacious when used as intended or will not cause crop damage. The Congress, by granting the EPA this waiver, clearly did not intend to preserve a product's effectiveness as a domain of FIFRA. On the contrary, it removed efficacy as a requirement and deleted the domain. Thus, when the EPA implemented the waiver, discontinuing efficacy tests as part of the label approval process, congressional intent was satisfied. This effectively removed from the ambit of the preemption clause all such claims for crop damage caused by using a pesticide as intended.

Stated differently, the waiver of efficacy testing as a requirement under the label approval process could be deemed to leave "no requirement" upon which preemption based on efficacy could be

founded. If there are no requirements under FIFRA, state causes of action for crop damages could not be preempted as imposing a requirement in addition to or different from those requirements imposed under the Act.

B. The Facts Are Also Similar

Not only is the preemption clause under FIFRA similar to the preemption clause in *Medtronic*, but the facts in that case are similar to those before this Court. The FDA allowed a pacemaker to be used without the normal rigorous testing to be performed based on the manufacturer's submissions that it was substantially equivalent to another or previous pacemaker. One of the significant holdings in *Medtronic* was that the defective design claims were not preempted because the FDA did not directly test the pacemaker or put it through the normal rigorous testing. Therefore, under *Medtronic*, state actions where the government has not acted are not preempted.

Similarly, the EPA under FIFRA does not test pesticides for safety to crops, delegating instead that control to the marketplace. Under present law, preemption only occurs when it is the clear and manifest purpose of Congress in areas where the EPA acts or regulates. All of the aforementioned are lacking.

The Supreme Court in *Wisconsin Public Intervenor v. Mortier,* 501 U.S. 597 (1999), made clear the limitations of FIFRA. It concluded that Section 136v of FIFRA resulted in a narrow preemptive overlap and Congress did not intend to occupy the entire field of pesticide regulation.

Clearly, the EPA's authority is not exclusive, nor are all state actions prohibited. *Id.* at 606-07.

In *American Cyanamid Co. v. Geye,* 79 S.W. 3d. 21 (Tex. 2002), the Texas Supreme Court dealt with a case where farmers tank-mixed a common combination of pesticides and sprayed targeted areas of crops, which resulted in phytotoxicity, causing damage and plant death. The Court held that Congress has permitted the EPA "to choose not to regulate product labeling with respect to how well a product works, that is, the product's 'efficacy'" and that "the EPA has chosen to define product efficacy to include 'target area phytotoxicity', that is, the effect of a particular product or combination of products on the crops that are deliberately sprayed." *Id.* at 23.

The Court acknowledged that the legislative history showed that the EPA required no crop safety data be submitted in the label approval process, concluding therefrom that crop safety was not an intended domain expressly preempted. *Id.*

Further, the Texas Supreme Court stated that the outcome determinative question before it of whether FIFRA preempted state law damage claims for crop damage did not require an examination of the scope of preemption but rather "the breadth of the congressionally created exception to express preemption." *Id.* The court concluded that "because the scope of FIFRA's preemption is dependent on what the EPA regulates, FIFRA does not preempt the Geyes' common law crop-damage claim." *Id.* at 29.

The *American Cyanamid* opinion accurately assessed the impact of ending efficacy review by EPA

on the scope of FIFRA preemption. Its reasoning, the Fifth Circuit's attempt to distinguish notwithstanding, it fully applicable to this case.

In the present case, discovery has not been conducted, nor has Dow Agrosciences advanced any proofs that EPA had specifically considered the effect upon crops from design, manufacturing methods or claims of safety, all of which formed the basis of the farmers' claims, i.e., strict liability, negligence, negligent misrepresentation and deceptive trade practices. These issues all dealt with the efficacy and safety claims of the herbicide Strongarm and the resulting crop damage from its use. Dow could not have carried its burden because the EPA waived the submission of all data and product testing for those areas with Congress' approval, leaving control of efficacy to the marketplace. Because the EPA does not address these issues during its labeling process, no basis for preemption could be established, and yet the Fifth Circuit mistakenly granted not only preemption but immunity to Dow for all damages caused to users of their product, even when used as intended. It is implausible that Congress would have ever intended this result, especially in light of the fact that it authorized the waiver of testing pesticides for effects upon crops.

Congress enacted FIFRA to protect the public and the environment from harm caused by dangerous substances. The Act attempts to prevent harm before it can happen, while state tort actions compensate victims after harm occurs. State tort actions based on a product's effectiveness were removed from the FIFRA umbrella by Congress, leaving them without federal protection and solely dependent on state law for a remedy.

It is illogical to believe that an Act whose purpose is to protect against harm from pesticides intentionally denies a remedy to those it sought to protect who have been harmed by pesticides.

This Court has the opportunity before it to end a long-term injustice fostered upon and borne by American farmers. That injustice was mistakenly institutionalized by the federal judicial system. Preemption of crop damage claims under FIFRA must end here, and the Court need do nothing more than enforce the intent of Congress clearly demonstrated in its amendments to FIFRA and the EPA's regulations that followed.

CONCLUSION

For the foregoing reasons, ATLA urges this Court to reverse the decision of the Fifth Circuit below.

Respectfully submitted,

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No. 03-388

In the Supreme Court of the United States

DENNIS BATES, ET AL.,

Petitioners,

vs.

DOW AGROSCIENCES LLC,

Respondent.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

BRIEF *AMICUS CURIAE* OF BASF CORPORATION IN SUPPORT OF RESPONDENT DOW AGROSCIENCES LLC

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INTEREST OF *AMICUS CURIAE*[1]

BASF Corporation (BASF) is a major supplier of agricultural products, including herbicides, fungicides, and other crop protection pesticides, to the farming industry. As a manufacturer of crop protection pesticides, BASF is subject to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y. BASF has an interest in any decision by this Court that could upset the comprehensive, carefully balanced federal/state regulatory scheme for pesticide labeling that Congress has established in FIFRA.

In addition, BASF now has pending before this Court a petition for a writ of *certiorari* that presents the issue of FIFRA preemption in a state consumer fraud class action. The Court's decision in this case may substantially affect BASF's pending case. *See BASF Corporation* v. *Peterson*, (petition for cert. filed July 16, 2004 (No. 04-81)). Indeed, given the breadth of Petitioners' attack on preemption, the decision may be dispositive of FIFRA preemption issues in *Peterson* and many other cases. BASF believes that it is

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[1] Pursuant to Sup. Ct. R. 37.6 ("Rule"), BASF states that no counsel for a party has authored this brief in whole or in part, and no person or entity other than BASF has made a monetary contribution to the preparation or submission of the brief. Pursuant to Rule 37.3(a), BASF has obtained consent of the parties to the filing of this brief. The parties have mutually consented to the filing of amicus briefs, and that consent has been filed with the Court.

important for the Court, in considering Petitioners' arguments, to have before it information about the wide variety of state-law claims that may conflict with the federal regulatory regime governing pesticide labeling. As we discuss herein, the *Peterson* case itself is a good example of a state-law damages claim, outside the traditional product liability context, that undermines EPA's ability to achieve FIFRA's goals through control over pesticide labeling.

The rule for which Petitioners argue would threaten EPA's exclusive authority under FIFRA to regulate the content and format of the labels on the nation's pesticides. That authority includes a broad array of powers that can address any problems on pesticide labels. FIFRA empowers EPA to adopt specific regulations mandating appropriate labels. If a pesticide manufacturer makes an error on a label, FIFRA provides the means for EPA to correct it.[2] If a pesticide manufacturer acts improperly with respect to a label, FIFRA provides EPA with the power to impose an appropriate sanction.[3] This authority serves Congress's goal of nationally uniform pesticide labeling.

Subjecting EPA-approved pesticide labels to a nationwide patchwork of jury-imposed common law modifications would effectively frustrate that goal of nationally uniform labeling. Such a result would severely disrupt the American pesticide market, resulting in higher

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[2] *See* 7 U.S.C. § 136d(b) (EPA may cancel a pesticide registration).

[3] *See id.*; 7 U.S.C. § 136k (EPA may stop sales and/or seize any pesticide found to be in violation of FIFRA); 7 U.S.C. § 136l(a)(1) (EPA may assess a civil penalty to registrants who violated FIFRA up to $5,000 per offense).

prices, voluminous and inconsistent product labels, reduced availability, and generally less certainty in a market that depends heavily on continuity. Such a scenario ultimately benefits no one—not the pesticide manufacturer and certainly not the consumer.

Accordingly, BASF submits this *amicus curiae* brief in support of Appellant Dow Agrosciences, LLC and requests this Court affirm the court of appeals ruling below.

SUMMARY OF ARGUMENT

FIFRA preempts all state law label "requirements in addition to or different from" those imposed by federal law. Such "requirements" may consist not only of positively enacted, prospective state statutes and regulations, but also of state common-law actions and other retrospective measures that necessarily affect pesticide labels.

Petitioners' attempt to draw a bright line between prospective and retrospective state-law "requirements," and their contention that FIFRA covers only the former, runs counter to the plain intent of FIFRA, this Court's precedent, and the substantial body of consistent and well-reasoned authority developed in the wake of this Court's decision in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). The key to preemption is not the form of the state action, but whether that action effectively "requires" a change in the federally-approved label. Contrary to Petitioners' assumption, the prospective or retrospective character of a state action neither dictates nor reveals whether it imposes such "requirements." Many state actions combine both prospective and retrospective elements. The bright-line test Petitioners urge thus is not tenable. Petitioners' argument would produce an anomalous result, where states are *not* permitted to establish by statute clear legislative requirements for pesticide labeling, but *are* permitted to impose *ad hoc*

labeling requirements through the back door by means of common law actions challenging those labels.

In addition, Petitioners' proposed bright-line test, with state regulations preempted on one side and state common-law actions permitted on the other, fails to account for the broad spectrum of approaches that states may take to addressing pesticide labels. From local regulations to state consumer fraud statutes, states take action in a number of ways that defy simple classification as prospective or retrospective, or as regulatory or common law. An approach based on such insubstantial distinctions threatens to turn FIFRA preemption into a mere pleading game in which attorneys will advance increasingly "creative" arguments to circumvent EPA's exclusive authority to regulate the scope and content of pesticide labeling, to the detriment of the environment, the nation's food supply, and farmers.

ARGUMENT

I. FIFRA'S EXPRESS PREEMPTION CLAUSE BARS STATES FROM IMPOSING "ANY REQUIREMENTS" FOR PESTICIDE LABELING "IN ADDITION TO OR DIFFERENT FROM" THOSE IMPOSED UNDER FIFRA, REGARDLESS OF THE SOURCE OF THE REQUIREMENT.

Petitioners expend a substantial portion of their brief to this Court trying to read the preemptive "requirements" language of FIFRA to contemplate, indeed to compel, two different classes of state control of pesticide labels: prospective regulation and retrospective regulation. Petitioners' Br. at 16-28. The relevant language of FIFRA provides:

> § 136v Authority of States
>
> (a) In general
>
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.
>
> (b) Uniformity
>
> *Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.*

7 U.S.C. § 136v(a) & (b) (emphasis added).

Petitioners ask the Court to construe this language as prohibiting one form of state intervention in labeling while permitting another. Although Petitioners' brief frames the issue in terms of regulations versus common law actions, Petitioners' Br. at 16-28, the distinction in analytical terms is really between prospective regulation of pesticide labels and retrospective regulation of those labels. Prospective regulation (which Petitioners concede is preempted by FIFRA, Summary of Argument, Petitioners' Br. at 14) looks forward and tells a pesticide manufacturer that, in the future, it must label its pesticide in a particular way or cannot label it in another. Such prospective regulation most often appears in the form of state statutes or regulations, but also includes other forward-looking state actions such as injunctions. *Cf., e.g., Lacey v. Lorillard Tobacco Co., Inc.*, 956 F. Supp. 956, 963-64 (N.D. Ala. 1997) (plaintiffs sought injunction requiring defendants to disclose an additional statement related to smoking and health not required by the Cigarette Labeling Act).

Retrospective regulation, in contrast, looks backward. Retrospective regulation tells a pesticide manufacturer—after the fact—that it should not have labeled its pesticide in the

way it did. Although common-law actions are perhaps the most common form of retrospective regulation in this context, there are others, as discussed below.

However the argument is framed, this Court has rejected the very distinction Petitioners urge. In *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992), this Court rebuffed the argument that common-law damages actions do not impose "requirement[s] or prohibition[s]" and that Congress intended only to trump "state statute[s], injunction[s], or executive pronouncement[s]." The Court declared that such a position "is at odds both with the plain words" of the statute and "with the general understanding of common law actions." *Id.* The Court explained that the term "requirements" in the 1969 Cigarette Act's preemption provision "sweeps broadly" and "easily encompass[es] obligations that take the form of common-law rules." *Id.*

A contrary holding would have anomalous consequences, as noted by Justice Breyer in *Medtronic v. Lohr*, 518 U.S. 470, 504-05 (1996) (concurring in part and concurring in the judgment):

> Imagine that, in respect to a particular hearing aid component, a federal MDA regulation requires a 2-inch wire, but a state agency regulation requires a 1-inch wire. If the federal law, embodied in the "2-inch" MDA regulation, preempts the state "1-inch" agency regulation, why would it not similarly pre-empt a state-law tort action that premised liability upon the defendant manufacturer's failure to use a 1-inch wire (say, an award by a jury persuaded by expert testimony that use of more than 1-inch wire is negligent)? The effects of the state agency regulation and

> the state tort suit are identical. *To distinguish between them for pre-emption purposes would grant greater power (to set state standards "different from, or in addition to," federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes.*

Id. at 504 (emphasis added). This allocation of power is not only arbitrary, it is fundamentally counterintuitive. It forbids statewide pesticide regulation by a state legislature or executive agency, with all their technical expertise, public policy considerations, and democratic controls, but permits *de facto* coercive pesticide regulation by a single jury, which has no inherent expertise on the topic and is provided only with the facts in a single, unique case.

As the Court observed in *Cipollone*, an award of damages can be "a potent method of governing conduct and controlling policy." 505 U.S. at 521 (quoting *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247). The Court further observed that "common-law actions of the sort raised by petitioner are premised on the existence of a legal duty, and it is difficult to say that such actions do not impose "requirements or prohibitions." *Id.* at 522 (citing W. Prosser, Law of Torts 4 (4th ed. 1971) and Black's Law Dictionary 1489 (6th ed. 1990)). The Court, in determining the scope of preemption under the 1969 Cigarette Act, therefore did not rely on any fictional distinctions between positive and common law, between acts and omissions, or even between intentional and unintentional torts. *Id.* at 523. Rather, the Court stated that the "central inquiry in each case is straightforward: we ask whether the legal duty that is the predicate of the common-law damages action constitutes a

'requirement or prohibition based on smoking and health. . . imposed under State law with respect to . . . advertising or promotion. . . .'" *Id.* at 523-24.

The word "requirements" in the 1969 Cigarette Act is, of course, also the operative term in FIFRA's labeling preemption clause, and nothing in the language of FIFRA suggests that Congress intended the term to mean anything different here. The lower courts have found little logic in the argument that the term in FIFRA differs in any substantive way from the identical term in the 1969 Cigarette Act. *See, e.g.*, *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 (5th Cir. 1994) ("We think this argument is sophistry."); *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 371 (7th Cir. 1993) ("[n]ot even the most dedicated hair-splitter could distinguish" the preemption clause of FIFRA from that interpreted in *Cipollone*); *Worm v. American Cyanamid Co.*, 5 F.3d 744, 748 (4th Cir. 1993) ("Any distinction between the two [common law and positive enactment] is 'illusory.'").[4]

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[4] Petitioners' argument that state law actions for damages do not impose "requirements" within the meaning of FIFRA's express preemption clause harks back to the faulty and almost universally rejected reasoning of the pre-*Cipollone* decision employed in *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir. 1984) (holding state tort suits based on inadequate labeling are not "requirements" preempted under § 136v(b)). The District of Columbia Circuit has since recognized that *Cipollone* repudiated *Ferebee's* central premise. *Waterview Management Co. v. F.D.I.C.*, 105 F.3d 696, 699 (D.C. Cir. 1997) (*Cipollone* "explain[ed] that damages actions can be used to enforce state regulations as effectively as other forms of preventive relief and thus damage actions must be preempted where positive enactments are preempted. . . .").

Even assuming *arguendo* that Petitioners' proposed distinction was logically tenable *and* that *Cipollone* had not foreclosed it, however, the bright line that Petitioners propose simply cannot be drawn. There is no clear distinction between prospective and retrospective regulation; there is instead a broad continuum of state actions that look forward and backward in different degrees. As Justice Scalia notes in *Cipollone*, "the problem is not simply the common law: Requirements could be imposed by state executive agencies as well, so long as they were operating under a *general* statute authorizing their supervision of 'commercial advertising' or 'unfair trade practices.' New Jersey and many other States have such statutes on the books." 505 U.S. at 553-54 (J. Scalia, concurring in part, and dissenting in part) (emphasis in original).

Even in the traditionally common law context of product liability claims alleging personal injury or property damage, like those involved here, states have taken different routes. Some have taken purely "retrospective" approaches to governing manufacturer conduct through common law theories of negligence and strict liability. *See, e.g., In re Shigellosis Litigation*, 647 N.W.2d 1, 11 (Minn. 2002); *Hagen v. TEXACO Refining & Marketing, Inc.*, 526 N.W.2d 531, 537 (Iowa 1999). Others have combined these common law causes of action into a single strict liability cause of action, either legislatively, *e.g.*, O.C.G.A. § 51-1-11; Connecticut Products Liability Act, Conn. Gen. Stat. §§ 52-572m—52-572q (2004), or judicially, *e.g.*, *Casrell v. Altec Indus.*, 335 So.2d 128, 132 (Ala. 1976).

Petitioners' attempted distinction breaks down further when pushed beyond the field of products liability. Most states have adopted consumer protection statutes directed at misleading commercial practices, and plaintiffs have increasingly invoked such statutes in asserting pesticide-

related claims. Indeed, Petitioners' claims in the present case include a claim under the Texas Deceptive Trade Practices Act. *See* Petitioners' Br. at 12-13.

These consumer fraud statutes blend prospective and retrospective regulation in a manner that defies the rigid lines that Petitioners ask the Court to draw. For example, the Minnesota Consumer Fraud Act, Minn. Stat. § 325F.68-70, offers a mixed bag of prospective and retrospective regulation. The chapter containing the statute bears the heading "*Prevention* of Consumer Fraud," *see* Minn. Stat. ch. 325F (emphasis added). The statute prospectively prohibits the use of any "misrepresentation" or "misleading statement" in connection with the sale of any merchandise (including, of course, pesticides), and provides avenues for injunctive relief. Minn. Stat. § 325F.70, subd. 1. On the other hand, the statute also provides a retrospective private cause of action similar to a common law claim, permitting consumers to recover damages based on conduct that a jury determines (after the fact) violated the statute. *See* Minn. Stat. § 8.31, subd. 3a.

These "mixed" sources of state action, with both prospective and retrospective elements, are commonplace in the current crop of lawsuits questioning pesticide labeling. Parties have invoked these "mixed" state consumer fraud statutes to ground claims that only a few years ago would have been the sole province of the common law.

BASF's pending petition for *certiorari* aptly illustrates the illusory distinction between prospective and retrospective state action in the supervision of pesticide labeling. In *BASF Corporation* v. *Peterson*, No. 04-81 (petition for cert. filed July 16, 2004), plaintiffs obtained a judgment of more than $52 million in a nationwide class action under the New Jersey Consumer Fraud Act because of perceived flaws in BASF's pesticide labeling. Plaintiffs complained that BASF failed to list on the EPA-approved

labeling of one of its products some of the crops for which EPA had authorized its use, thus preventing the plaintiffs from using it rather than a more expensive pesticide sharing the same active ingredient. 675 N.W.2d 57, 62 (Minn. 2004). From the Petitioners' perspective, the damages the *Peterson* plaintiffs sought were clearly "retrospective." But the coercive *prospective* effect of such a judgment could not be more clear: plaintiffs wanted a change in the label. Moreover, the change required by the judgment is flatly inconsistent with EPA's labeling regulations, which expressly grant manufacturers the flexibility to omit federally-registered uses from final product labeling.

Although the judgment in *Peterson* plainly imposed labeling requirements that are inconsistent with FIFRA and its regulations, the Minnesota Supreme Court ruled against preemption—in conflict with the decision below—on the basis that the plaintiffs relied on evidence of conduct and statements, such as BASF's advertising, that (although completely consistent with the label) "went beyond the label." 657 N.W.2d at 70. The overly narrow view of FIFRA preemption adopted by the state court in *Peterson* demonstrates the need for *this* Court to make a strong statement favoring *broad* preemption under FIFRA, rather than to adopt the restrictive view of Section 136v(b) for which the Petitioners argue.

Indeed, because the number and diversity of state statutes, regulations, common law actions, and executive directives potentially applicable to pesticide labeling has grown enormously in recent years, EPA's authority over pesticide labeling faces an increasing threat. Moreover, as this Court has recognized, states not only may regulate pesticides themselves, they may redelegate that authority to local authorities. *Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597 607-08, 612 (1991). Given such redelegation, a

wide variety of different types of regulation is not only possible but likely, and the question of preemption may arise from any one of them. In the face of that variety, any preemption jurisprudence that relies solely on a determination of prospective or retrospective effect will be hopelessly prolix and inherently unpredictable. The only rational and consistent approach to this question is the approach dictated by the language of the statute and adopted by the Fifth Circuit here: does the state action, whatever its character, impose a labeling requirement in addition to or different from that imposed by federal law?

II. THE REALITY OF FIFRA PREEMPTION GOES FAR BEYOND REGULATIONS AND COMMON LAW ACTIONS FOR DAMAGES.

In addition to positing an unrealistic distinction between prospective and retrospective state actions, Petitioners also fail to recognize the broad diversity of legal theories that courts and parties have sought to apply to issues involving pesticide labeling. By assuming *sub silentio* that the world of FIFRA preemption encompasses only state regulations and common law damage actions, Petitioners ignore the majority of the preemption issues that courts around the country actually deal with every day in pesticide cases. Adopting Petitioners' superficial bright line test would effectively turn the preemption issue in these varied cases from an examination of the substance of the claim into a mere pleading game.

Litigants routinely ask state courts to take a wide variety of state actions that affect or threaten to affect the existence, form, and content of pesticide labels. Petitioners' limited argument fails to adequately address or even acknowledge many of these. For example:

Negligent testing. One of the most common forms of state action regarding pesticide labels arises from a claim of

"negligent testing." *See, e.g., Taylor Ag. Indus. v. Pure-Gro*, 54 F.3d 555, 562 (9th Cir. 1995). Petitioners here even call their own claim "a classic case of inadequate testing," Pet. Br. at 44, but nevertheless never come to grips with the problem fundamental to such claims: they are generally premised on allegedly inadequate product labels. Plaintiffs may contend that a manufacturer should have done additional testing, but the claim often depends on the additional allegation that, if such testing had been done, the defendants would or should have placed additional or different warnings on the label. *See Dahlman Farms, Inc. v. FMC Corp.*, 240 F. Supp.2d 1012, 1019 (D. Minn. 2004) ("although couched in terms of negligent testing, [plaintiff's] first claim is premised on inadequate labeling, and it is therefore preempted by the FIFRA.").

Common law design defect. Plaintiffs also frequently invoke state court action against pesticide labels through claims based on "design defects." The substance of such a claim, however, often is not what the pesticide was or was not designed to do, but what the pesticide label said about the crops for which the pesticide was suitable, how the pesticide was to be applied, and the like. *See, e.g., Grenier v. Vermont Log Buildings, Inc.*, 96 F.3d 559, 564 (1st Cir. 1996); *Hopkins v. American Cyanamid*, 666 So.2d 615 (La. 1996). *See also Brierton v. Vermont Log Buildings, Inc.*, 1998 WL 611447, *3-4 (N.D. Ill Sept. 8, 1998) (holding that plaintiffs' claims for negligent or defective manufacture were in fact disguised labeling claims, and thus preempted).

Consumer fraud claims—sales of pesticides. Courts and plaintiffs have also employed state action through state consumer fraud statutes, premising claims on a manufacturer's alleged deceptive misrepresentations and/or omissions related to the safety of the pesticide. *See, e.g. Mortellite v. Novartis Crop Protection, Inc.*, 278 F. Supp.2d

390 (D. N.J. 2003) (alleging breach of the New Jersey Consumer Fraud Act for manufacturer's alleged deceptive representation that its product was safe to use as an insecticide on blueberry plants); *Anderson v. Dow Agrosciences, LLC*, 262 F. Supp.2d 1280, 1289 (W.D. Okla. 2003); *Dahlman Farms, Inc. v. FMC Corp.*, 240 F. Supp.2d 1012, 1020 (D. Minn. 2002). Again, although clad in the guise of consumer protection, these claims can directly question the federally approved pesticide labels.

Consumer fraud claims—failure to sell pesticide. Other plaintiffs have invoked a state consumer fraud statute against pesticide labeling in just the opposite way, to try to *force* a manufacturer to label a pesticide for a particular use against its will. In *Peterson v. BASF Corp.*, 675 N.W.2d 57 (Minn. 2004), *petition for cert. pending* (No. 04-81), the state courts sustained a claim based on the theory that BASF's pesticide labeling—EPA approved and fully compliant with FIFRA—implemented an unconscionable commercial practice.

In many ways, that Minnesota proceeding represents both the most alarming and at the same time most insidious type of state action against pesticide labels. The state court's action held in effect that BASF should not have labeled and advertised two products with the same active ingredient with different product names for different approved uses, even though EPA regulations (1) required BASF to give the two pesticides different names and labels based on the products' different chemical formulas, (2) explicitly allowed BASF to market the products with a subset of the EPA-approved uses on the label, and (3) strictly prohibited BASF from promoting any off-label use of its pesticides in its advertising. Such *ad hoc* regulation of pesticide labeling through state law-based jury verdicts necessarily erodes EPA's exclusive authority to regulate the content of pesticide labels. Yet, as discussed

above, the Minnesota Supreme Court ruled against preemption because the plaintiffs relied on evidence that, even though entirely consistent with the label, "went beyond the label." 657 N.W.2d at 70.

The *Peterson* case is not a mere flash in the pan; the attorney who brought the case has stated publicly that, because many manufacturers sell different pesticides with the same active ingredient, the premise of the case applies to "the entire industry."[5] To guard against an exponential increase in litigation attacking pesticide labeling, this Court should decisively affirm the Fifth Circuit's reasoning that FIFRA preempts state-law claims of *any* kind that attack pesticide labeling, even if the plaintiffs rely in part on advertisements and off-label statements, as long as the defendant could avoid liability by changing its labeling. This would help ensure that plaintiffs cannot circumvent FIFRA preemption by creative pleading—as the plaintiffs in *Peterson* have, so far, successfully done.

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[5] *E.g.*, *Minnesota High Court Approves $56 Million to U.S. Farmers in Fraud Suit*, CropChoice News (Feb. 22, 2004), *available at* http://www.cropchoice.com/leadstry5cbb.html?recid=2402; *Minnesota Appellate Court Approves $53 Million to U.S. Farmers in Consumer Fraud Class Action Against BASF*, The Soy Daily (Nov. 16, 2004), *available at* http://www.thesoydailyclub.com/Farm&Market/basf031420003.asp; PR Newswire, *Minnesota Supreme Court Approves $56 Million to U.S. Farmers in National Consumer Fraud Class Action*, L.A. Times (Feb. 19, 2004), *available at* http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=LATAGR.story&STORY=/www/story/02-19-2004/0002113056&EDATE=THU+Feb+19+2004,+03:21+PM.

State Court Injunctive Relief. Other litigants have asked courts to take direct state action imposing requirements on pesticide labels through the courts' injunctive powers. For example, in *Williams v. Dow Chemical Co.*, 255 F. Supp.2d 219, 231 (S.D.N.Y. 2003), the plaintiffs sought a permanent injunction requiring (1) implementation of a notice program to alert the public about risks of the pesticide and (2) implementation of appropriate labeling requirements on pesticide products advising the public of potential health risks.

Fraud on the Agency. Under this theory, a plaintiff asserts a common law claim that a defendant tortiously misled a federal agency into taking a particular action, such as approving a product or a label. In other words, the plaintiff asks the state to take action to effectively "correct" a mistake by the federal agency. A plaintiff may also assert that a defendant has "abused" federal regulations and that the regulations therefore lack any preemptive effect. This Court has already rejected one form of fraud-on-the-agency claim in *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) (finding MDA preempts claim that defendant misled FDA into designating one medical device as substantial equivalent of another),[6] but adoption of Petitioners' bright-line rule for

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[6] The Ninth Circuit has since extended the *Buckman* rationale to the context of FIFRA preemption. *See Nathan Kimmel, Inc. v. Dow Elanco*, 275 F.3d 1199, 1205 (9th Cir. 2002). (holding plaintiffs' claims, based on an allegation that defendant knowingly submitted false information to EPA to obtain an amended pesticide label, were preempted by FIFRA).

which plaintiffs argue would encourage parties to creatively replead the same substance in an effort to avoid the *Buckman* holding.

Claims to Cancel Registration. Litigants have asked courts to take state action against a pesticide label by effectively canceling the pesticide's federal registration. For example, in *Hardin v. BASF Corp.*, 290 F. Supp.2d 964 (E.D. Ark. 2003), the plaintiffs brought strict liability and negligence claims against the manufacturer of an herbicide that allegedly drifted over from nearby rice fields to plaintiffs' tomato fields. Despite resting their claim on the claimed inadequacy of the pesticide label's application instructions, *id.* at 970, plaintiffs argued that FIFRA preemption did not apply because, *inter alia*, (1) EPA had no authority to grant conditional registration for the herbicide; and (2) EPA registered the herbicide only because of political pressure. *Id.* at 972. As the district court noted, the argument asked the court to apply state law "to second guess the EPA's decision to grant BASF's application for registration of [the herbicide]." *Id.* (citations omitted). *See also Kuiper v. American Cyanamid Co.*, 131 F.3d 656, 666 (7th Cir. 1997) ("FIFRA does not allow states to second-guess EPA's labeling decisions under the guise of enforcing the requirements of FIFRA itself.")

State RICO Claims. Plaintiffs have even tried to invoke state RICO claims to prompt state action on pesticide labeling. *See Palmas y Bambu, S.A. v. E.I. du Pont de Nemours & Co.*, 881 So.2d 565 (Fla. Ct. App. 2004); *Williams v. Dow Chemical Co.*, 255 F. Supp.2d 219 (S.D.N.Y. 2003). As with the attempts at state action described above, such a RICO attack that tries to reach pesticide labels plainly implicates FIFRA preemption. As one federal court noted in addressing an analogous federal RICO claim:

> Recognition of a RICO cause of action premised on allegations that a pesticide manufacturer intentionally misrepresented or failed to disclose pertinent information concerning its product would obviously undermine the regulatory structure constructed by Congress. This would not only be inimical to the express congressional goal of uniformity in the regulation and sale of pesticides, but to allow a plaintiff to use RICO in such fashion would be to condone direct circumvention of the EPA's regulatory authority for the accomplishment of an end otherwise prohibited by Congress.

Jarman v. United Indus. Corp., 98 F. Supp.2d 757, 766 (S.D. Miss. 2000).

Other Types of State Action. Although the examples listed above are perhaps the most prominent types of state action that raise FIFRA preemption issues, the list does not stop there. Other theories plaintiffs have used or could use to invoke state action concerning federally approved pesticide labels include implied warranty of merchantability and fitness for a particular purpose, *e.g.*, *Papas v. Upjohn Co.*, 985 F.2d 516, 517 (11th Cir.), *cert. denied*, 510 U.S. 913 (1993), express warranties based on label statements, *e.g.*, *Welchert v. American Cyanamid, Inc.*, 59 F.3d 69 (8th Cir. 1995), negligent distribution, *e.g.*, *E.I. du Pont de Nemours & Co. v. Aquamar S.A.*, 881 So.2d 1 (Fla. Ct. App. 2004), and fraud on the market, *e.g.*, *Varacallo v. Massachusetts Mut. Life Ins. Co.*, 752 A.2d 807 (N.J. Super App. Civ. 2000).

In sum, this complex, subtle and varied mix of possible state statutory and common law actions belies Petitioners' implication that the world of FIFRA preemption is limited to state administrative regulations and common law

product-liability action. The crude, black-and-white classification that Petitioners propose would elevate the form of a state action above its substance, and would undermine EPA's exclusive jurisdiction over pesticide labeling. Any standard for analyzing whether FIFRA preempts a particular state action must focus on the substance of the claim and ask: does the state action, whatever its form, impose a labeling requirement in addition to or different from that imposed by federal law?

CONCLUSION

The court of appeals' opinion below, consistent with the largely uniform rulings of other federal courts of appeals and state courts of last resort, properly recognized that FIFRA preempts any state law cause of action that would subject a pesticide to "any requirements for labeling" that are "in addition to or different from" the FIFRA-required label. 7 U.S.C. § 136v(b). For all the reasons outlined above, this Court should affirm, making clear in its ruling that FIFRA preempts not only failure-to-warn claims, but also the wide variety of other state-law claims—such as the claims in the *Peterson* case—that attack pesticide labeling.

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No. 03-388

In the Supreme Court of the United States

DENNIS BATES, ET AL.,

Petitioners,

v.

DOW AGROSCIENCES LLC,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

INTEREST OF THE *AMICUS CURIAE*[1]

The Chamber of Commerce of the United States (the Chamber) is a nonprofit corporation organized under the laws of the District of Columbia and is the world's largest business federation. The Chamber represents an underlying membership of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases that raise issues of vital concern to the Nation's business community.

This is such a case. Many members of the Chamber depend on the preemption clause of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y, as protection against the imposition by state and municipal governments of diverse and burdensome requirements relating to the labeling of pesticides, herbicides, and other agricultural chemicals. For years, these businesses have relied on the lower courts' virtually uniform holdings – supported by a long line of this Court's own preemption decisions – that labeling requirements can be imposed as surely through common-law damages actions as through positive statutory enactments, regulations, and ordinances. Should this Court overturn those holdings as petitioners urge, the result will be the imposition of diverse and perhaps even conflicting obligations with respect to pesticide

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[1] The parties' letters of consent to the filing of this brief have been lodged with the Clerk. Under Rule 37.6 of the Rules of this Court, *amicus curiae* states that no counsel for a party has written this brief in whole or in part and that no person or entity, other than the *amicus curiae*, its members, or its counsel, has made a monetary contribution to the preparation or submission of this brief.

labeling that will subvert the national uniformity Congress intended FIFRA's preemption clause to preserve.

Moreover, many members of the Chamber that are not in the pesticide industry nevertheless have a substantial interest in the scope of FIFRA preemption because more than a dozen other federal statutes expressly preempt state "requirements" relating to product "labeling." See, *e.g.*, 15 U.S.C. §§ 1203(a), 1278 note, 1461, 1476(a), 2075(a), 2311(c); 21 U.S.C. §§ 343-1(a), 467e, 678, 1052, 14322(e); 42 U.S.C. §§ 6297(a), 6363(e)(1). Each of these provisions potentially gives rise to some of the same issues that are raised in this case. Because courts often interpret preemption clauses by looking to authoritative interpretations of comparably worded clauses in other statutes, the outcome of this case may be felt far beyond the pesticide industry. Thus, the Chamber has a strong interest in the proper resolution of the important issues raised in this case.

INTRODUCTION AND SUMMARY OF ARGUMENT

FIFRA is a "comprehensive regulatory statute" that "regulate[s] the use, as well as the sale and labeling, of pesticides; regulate[s] pesticides produced and sold in both intrastate and interstate commerce; [and] provide[s] for review, cancellation, and suspension" by the federal Environmental Protection Agency (EPA) of pesticide registrations. *Ruckelshaus* v. *Monsanto*, 467 U.S. 986, 991-92 (1984). An important part of FIFRA's comprehensive regulatory scheme is the creation of a national labeling regime to ensure that pesticide manufacturers may not be required to create separate product labels to comply with idiosyncratic or divergent requirements in every State. Toward that end, Congress included in FIFRA a preemption clause – appropriately titled "uniformity" – that bars the States from imposing on federally registered pesticides "*any* requirements for labeling or packaging" that are either "in addition to or different from those required under this subchapter." 7 U.S.C. § 136v(b) (emphasis added). As those words make clear, Congress intended Section 136v(b) "to *completely*

preempt state authority in regard to labeling and packaging." H.R. Rep. No. 92-511, at 16 (1971) (emphasis added).

I. In the decision below, the Fifth Circuit correctly recognized that States are capable of imposing "requirements" relating to pesticide labeling not only through positive enactments but also through duties imposed by the common law. Pet. App. 10a-11a & n.8. That holding follows ineluctably from this Court's analysis of indistinguishable statutory language in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992), and *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), as well as from many other decisions of this Court. It is also consistent with the rulings of the overwhelming majority of the lower federal and state courts. And this reading of Section 136v(b) ensures that FIFRA does not create a crazy quilt of preemption under which tort-law duties remain in place in the States that impose those obligations through the common law but are preempted in the many States that have enacted statutes codifying their common law of torts. Petitioners' various arguments for why this Court should radically alter the established landscape of FIFRA preemption law by holding Section 136v(b) excludes common-law "requirements" are all unavailing.

II. The Fifth Circuit was also correct in holding that "FIFRA's text does not define the scope of FIFRA's preemption clause to be a function of existing EPA regulations." Pet. App. 13a. Accordingly, petitioners are wrong in contending that there is no express preemption in this case because of the EPA's decision not to regulate target area phytotoxicity. By its plain terms, Section 136v(b) nullifies "any" requirements imposed by the States on pesticide labeling, whether those requirements are "different from" the federal requirements imposed "under this subchapter" or merely "in addition" to them. 7 U.S.C. § 136v(b). As we explain below, that language is best understood as requiring preemption even when there is no counterpart federal requirement in place. Congress knows full well how to make preemption contingent upon the existence of federal requirements dealing with the same risk or subject matter, has done so in other statutes, but has not done so in

FIFRA. Because the state-law requirements that petitioners seek to impose on Strongarm's labeling plainly are "in addition to or different from" the requirements imposed on that labeling by FIFRA itself, they are expressly preempted.

ARGUMENT

I. FIFRA PREEMPTS "REQUIREMENTS" IMPOSED THROUGH THE COMMON LAW

As this Court has instructed, "analysis of the scope of [a] preemption statue must begin with its text," *Medtronic* v. *Lohr*, 518 U.S. 470, 484 (1996), because "the plain wording of" an express preemption clause "necessarily contains the best evidence of Congress' pre-emptive intent." *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658, 664 (1993). FIFRA's preemption clause is contained in Section 136v, which is entitled "Authority of States" and provides in pertinent part:

> **(a) In general**
>
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.
>
> **(b) Uniformity**
>
> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

7 U.S.C. § 136v. "This subchapter" refers to Subchapter II, which consists of 7 U.S.C. §§ 136-136y.

Section 136v allows a State to prohibit the "sale or use" of any pesticide, and in certain circumstances allows it to approve a pesticide for use for a purpose other than those provided in the federal registration. See 7 U.S.C. § 136v(c). A State may not, however, "impose * * * any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. § 136v(b).

The clear purpose of Section 136v(b) is to ensure that under no circumstance will a pesticide manufacturer be induced to conform its product's labeling to idiosyncratic or divergent state-law standards. Nothing in the text suggests that preemption is limited to a particular *type* of standard; to the contrary, if uniformity is the goal, the most natural interpretation is that Section 136v(b) preempts any aspect of state law – be it positive enactment or common law – that would require a pesticide manufacturer to change its federally approved label. And that, of course, is what the preemption clause says: it preempts "any" state requirement that adds to or differs from any federal requirements imposed under FIFRA.

Petitioners, however, contend that the word "requirements," understood in context, "encompasses only rules issued pursuant to positive law, such as statutes and regulations." Pet. Br. 14. In an effort to support that position, petitioners advance a variety of arguments based on this Court's decisions involving other preemption clauses, the text and structure of FIFRA, the congressional purposes underlying the statute, and the legislative history. None of these arguments is persuasive.

A. This Court's Decisions Clearly Establish That Common-Law Duties Impose "Requirements"

Twice in recent years litigants have urged this Court to limit the word "requirements" in a preemption clause to positive enactments. See *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992); *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996). Twice this Court has refused. These decisions – and the precedents on which they rely – are controlling here.

1. *Cipollone* involved a suit brought under New Jersey common law against cigarette manufacturers seeking recovery under theories of design defect, failure to warn, express warranty, fraudulent misrepresentation, and conspiracy to defraud. The defendants contended that the Federal Cigarette Labeling and Advertising Act of 1965 ("1965 Act"), and its successor, the Public Health Cigarette Smoking Act of 1969 ("1969 Act"), expressly preempted those common-law claims.

As with FIFRA, the purpose of both Acts was to ensure uniformity in labeling. Section 2 of the 1965 Act stated that it was intended to "protect[] the national economy from the burden imposed by diverse, nonuniform, and confusing cigarette labeling and advertising *regulations*." 15 U.S.C. § 1331 (1982 ed.) (emphasis added) (quoted in *Cipollone*, 505 U.S. at 511 n.5). Toward that end, the 1965 Act contained a preemption clause providing that "[n]o *statement* relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity of the provisions of this Act." 15 U.S.C. § 1334(b) (1965) (emphasis added). This Court concluded that the reference to "statement[s] * * * in the advertising," read in light of other provisions of the statute (including the statement of purpose, which as just noted referred to "regulations"), evinced a congressional intent to "supersede[] only positive enactments by legislatures or administrative agencies." 505 U.S. at 518-19.

The 1969 Act, however, substantially broadened the 1965 Act's preemptive scope. Without changing the declared purpose of protecting the economy from the burden of nonuniform "regulations," the 1969 Act replaced the 1965 Act's preemption clause with a new provision stating:

> No *requirement* or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with * * * of this Act.

15 U.S.C. § 1334(b) (emphasis added). The plaintiff in *Cipollone* argued that, like the 1965 Act, the 1969 Act did not preempt common-law actions because they do not impose "requirement[s] or prohibition[s]," and Congress intended only to preempt state positive law. In rejecting that submission, this Court explained that "[t]he phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words *easily encompass* obligations that take the form of common-law rules." *Id.* at 521 (plurality) (emphasis added); *id.*

at 548-49 (Scalia, J., joined by Thomas, J., concurring in the judgment in part and dissenting in part) (agreeing with that conclusion). Plaintiff's argument, the Court added, was "at odds both with the plain words" of the statute and "with the general understanding of common-law damages actions." *Id.* at 521; *id.* at 548-49 (per Scalia, J.).

2. A majority of this Court again rejected a claimed exclusion for common-law requirements in *Medtronic*, which involved the preemption clause of the Medical Device Amendments (MDA), 21 U.S.C. § 360k(a). Entitled "State and local requirements respecting devices," the MDA's preemption clause provides in relevant part (*ibid.* (emphasis added)):

> [N]o state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use *any requirement* – (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Writing for four Justices, Justice O'Connor explained that "state common-law damages actions operate to *require* manufacturers to comply with common-law duties." 518 U.S. at 510 (concurrence and dissent) (emphasis added). "If § 360k's language is given its ordinary meaning," she reasoned, "it *clearly* pre-empts any state common-law action that would impose a requirement different from, or in addition to, that applicable under the FDCA – just as it would pre-empt a state statute or regulation that had that effect." *Id.* at 511 (emphasis added). Writing separately, Justice Breyer agreed with Justice O'Connor and three other Justices that "[t]he statute's language, read literally, supports th[e] conclusion" that "the MDA will sometimes pre-empt a state-law tort suit." *Id.* at 504 (concurring in part and concurring in the judgment).

In casting the fifth vote for this reading, Justice Breyer also explained that "a contrary holding would have anomalous

consequences." 518 U.S. at 503. In words that apply with equal force here, Justice Breyer reasoned:

> Imagine that, in respect to a particular hearing aid component, a federal MDA regulation requires a 2-inch wire, but a state agency regulation requires a 1-inch wire. If the federal law, embodied in the "2-inch" MDA regulation, pre-empts the state "1-inch" agency regulation, why would it not similarly pre-empt a state-law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire (say, an award by a jury * * * that use of a more than 1-inch wire is negligent)? *The effects of the state agency regulation and the state tort suit are identical.* To distinguish between them for pre-emption purposes would grant greater power * * * to a single state jury than to state officials acting through state administrative or legislative lawmaking processes.

Ibid. (emphasis added). That "result," Justice Breyer added, would be "anomalous." *Ibid.*

3. The Court's decisions in *Cipollone* and *Medtronic* build on older decisions that recognize the same principle or acknowledge the clear regulatory effect of common-law judgments. In *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236 (1959), the Court observed that "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." *Id.* at 247. Similarly, in *Norfolk & Western R. Co.* v. *Train Dispatchers*, 499 U.S. 117 (1991), the Court held that the phrase "all other law, including State and municipal law" simply "does not admit of [a] distinction * * * between positive enactments and common-law rules of liability." *Id.* at 128. Indeed, "[a]t least since *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938), [the Court] ha[s] recognized the phrase 'state law' to include common law as well as statutes and regulations." *Cipollone*, 505 U.S. at 522.[2]

In *CSX Transp.* v. *Easterwood*, 507 U.S. 658 (1993), this Court examined the preemption clause of the Federal Railroad Safety Act (FRSA), which provides that federal regulations may preempt any state "law, rule, regulation, order, or standard relating to railroad safety." 23 U.S.C. § 434. Citing *Cipollone*'s recognition that the word "requirement" "easily" includes common-law claims, the Court held that "[l]egal duties imposed upon railroads by the common law fall within the scope of [the FRSA's] broad phrases." 507 U.S. at 664. Together with *Cipollone* and *Medtronic*, these decisions defeat petitioners' argument that the word "requirements" in Section 136v(b) describes only positive enactments.

4. In light of the foregoing decisions, it is not surprising that all nine federal circuits that have considered the question have agreed with the Fifth Circuit that FIFRA preempts common-law "requirements." See Br. in Opp. 15-16 & n.13 (collecting cases). Nor is it surprising that 27 out of 29 state appellate courts have reached the same conclusion. *Id.* at 16-17 & nn. 15-16 (same).

5. *Sprietsma* v. *Mercury Marine*, 537 U.S. 51 (2002), upon which petitioners rely for the proposition that Congress "commonly distinguishes between state positive and common law for preemption purposes" (Pet. Br. 20), does not overrule or undermine the foregoing precedents nor does it support petition-

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[2] Other decisions of this Court have consistently recognized that the common law imposes standards and requirements. See, *e.g.*, *Asahi Metal Indus. Co.* v. *Superior Court*, 480 U.S. 102, 114-15 (1987) (quoting California Supreme Court's description of product-liability actions as ensuring compliance "with the state's safety standards"); *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984) ("imposition of a state standard in a damages action"); *United Gas Improvement Co.* v. *Continental Oil Co.*, 381 U.S. 392, 400 (1965) ("common law standards"); *Shenker* v. *Baltimore & Ohio R.R.*, 374 U.S. 1, 11 (1963) ("stricter negligence standards of common law").

ers' strained interpretation of FIFRA. In *Sprietsma*, this Court held that the Boat Safety Act (BSA) does not preempt common-law claims. But the BSA and its preemption clause were materially different from FIFRA. The BSA provided that "a State * * * may not establish, continue in effect, or enforce *a law or regulation* establishing a recreational vessel or associated equipment performance or other safety standard or imposing a requirement for associated equipment * * * that is not identical to a regulation prescribed under section 4302 of this title." 46 U.S.C. § 4306 (emphasis added).

Focusing on the highlighted phrase, this Court gave three reasons why common-law claims were not preempted. First, "the article 'a' before 'law or regulation' implies a discreteness – which is embodied in statutes or regulations – that is not present in the common law." 537 U.S. at 63. Second, Congress's use of the terms "law" and "regulation" together "indicate[d] that Congress preempted only positive enactments," because an interpretation of "law" that included "common law" might also include "regulations," which would create a disfavored redundancy. *Ibid.* And third, the BSA includes a "savings" clause that specifically refers to "liability at common law" (46 U.S.C. § 4311(g)). See 537 U.S. at 526-27. The "contrast between [the savings clause's] general reference to 'liability at common law' and the more specific and detailed description of what is preempted" by the preemption clause, the Court explained, further "indicates" that Congress intended the latter to cover only "performance standards and equipment requirements imposed by statute or regulation." *Ibid.*

None of these reasons has any application to this case. FIFRA does not include any "savings" clause, much less one that refers in potentially contrasting fashion to "liability at common law." And FIFRA's preemption clause is worded quite differently from the BSA's. Section 136v(b)'s use of the broad phrase "any requirements" implies no discreteness. Its use of "requirements" without pairing it with other terms avoids the need to interpret multiple terms in light of each other (and avoid redundancy).

Indeed, the operative language of Section 136v(b) far more closely resembles the wording of the provisions at issue in *Medtronic* ("no state * * * may establish * * * any requirement * * * which is different from, or in addition to, any requirement applicable under this chapter"), and in *Cipollone* ("No requirement * * * shall be imposed under State law * * * "), which this Court has ruled clearly encompass requirements imposed under the common law. Moreover, this case is an even stronger one for express preemption of common-law "requirements" than *Cipollone*, because Congress's avowed purpose underlying the 1969 Cigarette Labeling Act's preemption clause was to ensure uniformity of state "regulations," whereas Congress intended Section 136v(b) "to *completely preempt* state authority in regard to labeling and packaging." H.R. Rep. No. 92-511, at 16 (1971) (emphasis added). *Cipollone* and *Medtronic* are thus controlling.[3]

B. Nothing In The Text Or Structure Of FIFRA Supports Petitioners' Request For The Exclusion Of Common-Law Requirements

Faced with this Court's case law and the tidal wave of lower-court decisions described above, petitioners fall back on a hodgepodge of arguments based on the language and structure

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[3] Petitioners' related but inconsistent suggestion (Pet. Br. 14, 16, 17) that "damages actions" are not preempted by Section 136v(b)– including, presumably, damages actions based on state product liability *statutes* – rests on the mistaken assumption that a remedy can be permitted to proceed even though the underlying right, obligation or requirement it seeks to enforce has been nullified by Congress. It also mistakenly assumes that the requirement to pay damages is not a "requirement." See Dinh, *Regulatory Compliance as a Defense to Products Liability: Reassessing the Law of Preemption*, 88 GEO. L. J. 2085, 2114 (2000) ("[T]he effect of tort liability on primary conduct is the same as a statutory prescription or regulatory standard."). In any event, this variation of petitioners' argument was also rejected in *Medtronic*. See 518 U.S. at 510 (O'Connor, J.) ("state common-law *damages actions* operate to *require* manufacturers to comply with common-law duties") (emphasis added); accord *id.* at 504 (Breyer, J.).

of FIFRA for why, in their view, Section 136v(b) must be interpreted as excluding requirements imposed under state common law or tort law. See Pet. Br. 17-20, 22-25. All of these arguments are meritless.

1. Petitioners make much of the fact that the word "requirements" appears "75 times in the remainder of FIFRA, * * * and each time refers only to * * * statutory and regulatory enactments." Pet. Br. 22. They also point out that "Congress used the term 'requirements' in § 136v(b) to refer to both state and FIFRA requirements," and argue that "[i]t would be unnatural to read the word 'requirements' more broadly in reference to a source of state law than for the federal government." Pet. Br. 18. Accordingly, petitioners argue, Section 136v(b)'s reference to state "requirements" should be understood as excluding requirements based in the common law.

This argument fails for at least three reasons. *First*, although petitioners note that a plurality of this Court in *Medtronic* found a similar argument persuasive (Pet. Br. 24-25), they neglect to mention that the majority *implicitly rejected* this argument in holding that the MDA's preemption clause covers common-law requirements. Indeed, precisely the same argument was made in *Medtronic* by the plaintiff based on multiple other uses of the word "requirement" throughout the MDA. See Nos. 95-754, 95-886 Br. for Cross-Pet. Lohrs, at 11-12, 16-19; Nos. 95-754, 95-886 Reply Br. Cross-Pet. Lohrs, at 8-9. Nor are petitioners correct in asserting that the "textual evidence here" is stronger. Scores of other provisions in the MDA refer to "requirements" and, in so doing, describe requirements imposed by statute or by the administering agency (there, the FDA). See, *e.g.*, 21 U.S.C. §§ 360(*l*), 360(m)(1), 360(o)(2), 360c(b)(1)(B), 360c(c)(2)(A), 360c(d)(2)(A), 360d(c)(1)(A), 360e(a), 360h(b)(2)(B), 360h(c), 360i(a)(4), 360j(a).[4]

[4] Had the Court in *Medtronic* adopted petitioners' mode of analysis, it might have reached the opposite result on the question whether the plaintiffs' design claim was preempted. As the manufacturer pointed out, other provisions of the MDA refer to "requirements" imposed on so-called "510(k)" medical devices (which are cleared for marketing based on "substantial equivalence"). See Nos. 95-754, 95-886 Br. for Pet. Medtronic, at 31-32. Yet this Court held that the 510(k) clearance process imposes no design requirements on a device. 518 U.S. at 492-94.

Second, the Court in *Medtronic* also rejected petitioners' narrower argument based on the use of the word "requirements" within the *preemption clause itself* to refer to both state and federal obligations. That variant is flawed because it ignores qualifying language in FIFRA's preemption clause: "Such State shall not impose * * * any requirements for labeling or packaging in addition to or different from those required *under this subchapter*." 7 U.S.C. § 136v(b) (emphasis added). It is the italicized language that creates the limit on the federal "requirements" to which Section 136v(b) refers, not the words "those required" (a synonym for "requirements"). The Solicitor General made the same point in *Medtronic* in successfully urging this Court not to accept a similar reading of the MDA's preemption clause, which refers, on the federal side, to "any requirement *applicable under this chapter* to the device" (21 U.S.C. § 360k(a) (emphasis added)):

> The problem with [the Lohrs'] reasoning is that the limitation on the type of federal provisions that have preemptive effect is not attributable to the term "requirement." It is, instead, attributable to the words that modify "requirement." A state provision may be preempted only by a federal requirement "applicable under this chapter." 21 U.S.C. 360k(a). It is the latter phrase that limits the federal provisions having preemptive force to those imposed by the FDCA and implementing regulations, rather than by common law.

Nos. 95-754, 95-886 U.S. Br. 16-17. The same is true here.

Third, petitioners' argument overlooks the obvious reason why the federal "requirements" FIFRA refers to are traceable to either the statute or to EPA's regulations. It should come as no surprise that a federal statute that imposes requirements on

manufacturers and empowers an administrative agency to regulate in the public interest (by imposing additional requirements) would use the term "requirement" to refer exclusively to statutory and regulatory mandates. Those, after all, are the *only* kinds of "requirements" that such a regime imposes. It does not follow, however, that the broad term "requirements" cannot encompass something more when applied to the obligations that a State may impose through its court system. Any limitation on the federal side of the equation to obligations imposed by the statute or an administrative agency, in other words, is a function of the limitations on the federal scheme and the kinds of requirements it is capable of producing. It is also a function of the very limited role that federal "common law" plays under our system of government. See *Boyle* v. *United Technologies Corp.*, 487 U.S. 500, 504-05 (1988).[5]

2. Next, petitioners contend that because Section 136v(b) refers to "[s]uch State[s]" that impose "regulation[s]" under Section 136v(a), the state-law "requirements" preempted by Section 136v(b) must be considered a subset of "regulation[s]." Pet. Br. 17; see also *id.* at 25 n.14 (suggesting that the "requirements" mentioned in Section 136v(b) must "stem[] from a 'regulation' otherwise permitted in § 136v(a)"). Because "regulation[s]" are positive enactments, they argue, "requirements" must be as well. This argument has been repeatedly rejected by the lower courts. See, *e.g.*, *Taylor AG Indus.* v. *Pure-Gro*, 54 F.3d 555, 560-61 (9th Cir. 1995); *King* v. *E.I. Dupont De Nemours & Co.*, 996 F.2d 1346, 1349-50 (1st Cir.), cert. dismissed, 510 U.S. 985 (1993); *Goodwin* v. *Bacon*, 896

[5] Petitioners argue that even "FIFRA's references to 'requirements' *of state law* encompass only positive law commands" (Pet. Br. 24), but as their citations make clear, the requirements themselves are imposed upon States *by FIFRA*. See, *e.g.*, 7 U.S.C. §§ 136i(a)(1), 136w-2(a); cf. *id.* § 136w-5 (making reference, in language that is clearly distinguishable, to a State's "requirements *for training*") (emphasis added). Only in Section 136v(b) – FIFRA's preemption clause – did Congress have cause to refer to requirements imposed on pesticides *by States*, and that instance therefore requires an analysis independent of the other provisions.

P.2d 673, 680 (Wash. 1995); *Jenkins* v. *Amchem Prods., Inc.*, 886 P.2d 869, 880 (Kan. 1994), cert. denied, 516 U.S. 820 (1995). It fails for at least three reasons.

First, petitioners' "subset" interpretation would give the words "regulation" and "requirement[]" precisely the same meaning. In substance, States would be free to impose "sale or use" regulations as long as those regulations did not take the form of labeling regulations. That might be a coherent statutory scheme, but it is not the one Congress enacted. Congress chose to use the word "requirements" rather than "regulation[s]" in Section 136v(b), and it is axiomatic that "[t]he use of different words within related statutes generally implies that different meanings were intended." *United States* v. *Bean*, 537 U.S. 71, 76 (2002) (quoting 2A N. SINGER, SUTHERLAND ON STATUTES AND STATUTORY CONSTRUCTION § 46.06, at 194 (6th ed. 2000)). Petitioners' argument ignores this principle.

Second, petitioners' argument overlooks the fact that "regulation[s]" in Section 136v(a) refers only to regulations governing "sale or use." Labeling requirements, however, are entirely distinct from – and are not a subset of – "sale or use" regulations. For example, this Court has stated that FIFRA "regulated the use, as well as the sale and labeling, of pesticides," making clear that the concepts of sale, use, and labeling are analytically distinct. *Wisconsin Publ. Intervenor* v. *Mortier*, 501 U.S. 597, 601 (1991) (quoting *Ruckleshaus* v. *Monsanto Co.*, 467 U.S. 986, 991-92 (1984)).

Indeed, petitioners' "subset" interpretation is in severe tension with the reasoning of *Mortier*. There, this Court held that FIFRA does not impose "field" preemption because such an interpretation would render Section 136v(b) superfluous. The Court explained:

> Taking [field] pre-emption as the premise, § 136v(a) would * * * grant States the authority to regulate the "sale or use" of pesticides, while § 136v(b) would superfluously add that states did not have the authority to regulate "labeling or packaging," an addition that would have been

> doubly superfluous given FIFRA's historic focus on labeling to begin with.

501 U.S. at 613. Under this Court's reasoning in *Mortier*, labeling requirements are *not* a subset of "sale or use" regulations. If they were, even under a field preemption theory, labeling requirements would survive preemption as a subset of the "sale or use" regulations carved out by Section 136v(a). In that event, Section 136v(b) would be *necessary* – not superfluous – to ensure that States could not impose divergent labeling requirements. Thus, if this Court was correct in *Mortier* that field preemption would render Section 136v(b) superfluous, it can *only* be because the subset theory is incorrect.

Third, given that labeling is a concept distinct from sale and use, petitioners' "subset" interpretation would yield absurd results. Section 136v(b) would preclude labeling requirements for only "[s]uch State[s]" that impose "sale or use" regulations; States that elect not to issue such regulations would be free to impose labeling requirements – even in the form of statutes and regulations. Congress surely did not intend that result. The better reading of "[s]uch State" in Section 136v(b) treats it as a synonym for "[a] State," the phrase used in Section 136v(a). Congress used "[s]uch State" merely to avoid repetition.

3. Observing that Section 136v(a) empowers States to ban the sale or use of a pesticide entirely, petitioners next contend that "it makes no sense to construe § 136v(b) to foreclose the *lesser* regulatory effects that flow from damages actions that enable the pesticide manufacturer to choose to sell its products while assuming the risk of common-law liability[.]" Pet. Br. 18-19. But that argues far too much, for it applies with equal force to state labeling requirements imposed by statute or regulation that are enforceable through fines or monetary penalties.

C. Petitioners' Arguments Based On The Legislative History Are Unpersuasive

Next, petitioners argue that FIFRA does not preempt "requirements" imposed by the common law because the "legislative history of the 1972 FIFRA amendments" contains

no mention of the possibility that "the proposed legislation would shield pesticide manufacturers from product liability tort suits." Pet. Br. 26. Congress's silence on this score is especially significant, petitioners suggest, because of the historical backdrop of tort litigation involving pesticides. Pet. Br. 4-5, 25-27. Notably, in advancing these arguments petitioners make no effort to explain how their interpretation of FIFRA can be reconciled with the evidence in committee reports making clear that Congress intended Section 136v(b) "to *completely preempt* state authority in regard to labeling and packaging." H.R. Rep. No. 92-511, at 16 (1971) (emphasis added); see *Conroy* v. *Aniskoff*, 507 U.S. 511, 519 (1993) (Scalia, J., concurring in the judgment) (comparing use of legislative history to "entering a crowded cocktail party and looking over the heads of the guests for one's friends"). But even putting aside petitioners' selective use of the legislative history, their arguments are mistaken.

1. This Court has routinely refused to take the "extraordinary" step of "requir[ing] legislative history to confirm the plain meaning of" a statute. *Bourjaily* v. *United States*, 483 U.S. 171, 178 (1987). See also *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 669 n. 2 (1990) (statute can have effects not explicitly mentioned in its legislative history). Moreover, the Court is loathe to draw inferences from congressional silence or inaction. See also *Garcia* v. *United States*, 469 U.S. 70, 78 (1984) (courts are "not willing to narrow the plain meaning of * * * [a] statute on the basis of a gestalt judgment as to what Congress probably intended"). Where, as here, Congress has enacted a statutory preemption clause that includes broad language that encompasses without qualification all types of state "requirements," and does not exclude common-law duties, there is even less reason to attach any importance to silence in the legislative history concerning common-law duties.

2. As if that were not enough, this Court has twice *rejected* the argument that a preemption clause does not reach state common law because legislative history includes no mention of the preemption of common-law duties. In *Cipollone*, the Court held that common-law "requirements" were preempted by the

1969 Cigarette Act even though portions of the legislative history suggested that "Congress was primarily concerned with positive enactments by States and localities," 505 U.S. at 521 (opinion of Stevens, J.), and there was no explicit reference in the legislative history to common-law damages actions, *id.* at 540 (opinion of Blackmun, J.). Nevertheless, because the Act's language "plainly reache[d] beyond" positive enactments, 505 U.S. at 521 (opinion of Stevens, J.), the Court held that common-law claims were subject to preemption.

Similarly, in *Medtronic*, a majority of the Court rejected the same argument in holding that the MDA's preemption clause covers common-law "requirements." To be sure, as petitioners note in their brief (at 27), four Members of the Court thought it was significant that "nowhere in the materials relating to the Act's history have we discovered a reference to a fear that product liability actions would hamper the development of medical devices." 518 U.S. at 490 (plurality opinion of Stevens, J.). The same four Justices also thought it was "spectacularly odd" that there was no mention in the legislative history "particularly since Members of both Houses were acutely aware of ongoing product liability litigation." *Id.* at 491. Notably, however, a majority of the Court was not persuaded by these points and ruled that common-law requirements *are preempted*. See also *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374, 385 n.2 (1992) (Airline Deregulation Act preempts state advertising standards even though legislative history contained no statements specifically addressing state regulation of advertising).

3. Petitioners fare no better in their invocation of a long history of tort litigation involving pesticides.[6] That argument

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[6] Petitioners argue that before the 1972 amendments, "it was well-settled that FIFRA's labeling requirements set only minimum standards." Pet. Br. 25-26. Even under petitioners' reading of Section 136v(b), however, it is clear that Congress intended to alter that background principle (by preempting "different" labeling requirements imposed by state statute even if they are less stringent than applicable federal requirements).

overlooks the seismic changes in the American law of product liability that occurred beginning in the 1960s, just before Congress amended FIFRA. As the American Law Institute has correctly observed, it was not until the early 1960s that "American courts began to recognize that a commercial seller of any product having a manufacturing defect should be liable in tort for harm caused by the defect regardless of the plaintiff's ability to maintain a traditional negligence or warranty action." RESTATEMENT OF THE LAW (THIRD): PRODUCTS LIABILITY § 1, cmt. a (1998). Moreover, while "liability for manufacturing defects has a long history in the common law," the "[i]mposition of liability for design defects and for defects based on inadequate instructions was relatively infrequent until the late 1960s and early 1970s." *Ibid.* The widespread acceptance of strict liability, the elimination of the privity requirement (allowing consumers to bring actions directly against product manufacturers who were one or two steps removed in the distribution chain), and the growing use of design defect and failure-to-warn theories, all followed closely upon the ALI's publication in 1965 of the RESTATEMENT (SECOND) OF TORTS, which included the highly influential Section 402A.

To the extent Congress has acted against a backdrop of tort litigation predating these seminal developments, it was tort litigation that looked quite different. By their very nature, manufacturing defect cases tend to focus on the failure of a single product unit (or batch of products) to conform to the manufacturer's own design specifications. In contrast, claims of design defect and inadequate labeling ordinarily target shortcomings of *all* specimens of a product, and they call upon juries (or judges) to determine whether "the manufacturer's design specifications * * * themselves create unreasonable risks" (an inquiry that, in turn, "requires reference to a standard outside the specifications"). RESTATEMENT OF THE LAW (THIRD): PRODUCTS LIABILITY § 2, cmt. d; see also *id.* § 1, cmt. a. To decide such issues, juries (or judges) must engage in risk-utility balancing that is analogous to the inquiry conducted by a regulatory agency (except that it occurs within the narrow

confines of a single tort lawsuit, with its evidentiary limitations and exclusive focus on the plaintiff's specific injury).

It is these fundamental changes in American product liability law, together with the more recent rise of mass tort litigation and large punitive damages awards, that have transformed state tort law into one of the most powerful means of imposing legal requirements on manufacturers and other business defendants. See Hensler, *The New Social Policy Torts: Litigation As A Legislative Strategy, Some Preliminary Thoughts On A New Research Project*, 51 DEPAUL L. REV. 493, 498 (2001) ("What seems to most distinguish the new tort actions from conventional damage class actions is that, in addition to seeking damages and enforcement of current regulations, the plaintiffs seek to change the rules that govern industry-wide business practices."). In recent years, for example, plaintiffs (including state attorneys general) in tort suits brought against the tobacco, gun, and managed care industries have sought changes, respectively, in the defendants' marketing policies, product design, and coverage decision-making processes. *Ibid.* In light of these developments, the pre-1972 decisions cited by petitioners seem almost quaint.[7]

Given the increasingly significant regulatory impact of tort law, petitioners' proposed distinction between positive regulations and common-law requirements is difficult to view as anything other than an elevation of form over substance. The timing of these developments might also help to explain why "no witness or Member of Congress ever suggested that the [1972 FIFRA amendments] would shield pesticide manufacturers from product liability tort suits." Pet. Br. 26.[8]

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[7] Compare also No. 04-81 Pet. for Certiorari, *BASF* v. *Peterson* (filed July 16, 2004) (seeking review of decision upholding Minnesota jury's $52 million judgment against pesticide manufacturer for alleged labeling-related defects, in nationwide class action based solely on New Jersey law).

[8] Petitioners suggest that upholding the preemption defense in this case would be "contrary to Congress's central aim in the 1972 Act to protect the public from dangerous chemicals." Pet. Br. 14. But Congress had multiple aims in enacting and amending FIFRA – including the creation of a uniform national regime of labeling. Moreover, Congress chose *other means* of achieving the goal of protecting the public – such as the conferral of greater regulatory authority on the federal government.

D. Excluding Common-Law Requirements Would Lead To Absurd Results

In light of the powerful regulatory function played by tort litigation today, it would be anomalous to read FIFRA's preemption clause as excluding requirements based in state common law. But there are four other reasons why that result is nonsensical and would lead to absurd results by creating an irrational and judicially unmanageable patchwork of preemption that Congress could not possibly have intended.

First, many States have codified their common-law tort regimes. See, *e.g.*, ARIZ. REV. STAT. ANN. §§ 12-681 to -686 (1992); CONN. GEN. STAT. §§ 52-572m to 52-572q (2004); IND. CODE ANN. § 33-1-1.5-1 to 33-1-1.5-10 (West 1983 & Supp. 1996); LA. REV. STAT. ANN. §§ 9:2800.51 to 9:2800.59 (West 1991); OHIO REV. CODE ANN. §§ 2307.71 to 2307.80 (Baldwin 1996); S.C. CODE ANN. §§ 15-73-10 to 15-73-30 (Law. Co-op. 1993). See generally Hermann & Ritts, *Preemption and Medical Devices: A Response to Adler and Mann*, 51 FOOD & DRUG L.J. 1, 9 n.41 (1996) (collecting other statutes). Under petitioners' view, tort requirements in these jurisdictions would be preempted but identical common-law requirements in neighboring States would not. Why should such an absurd design be attributed to Congress?[9]

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[9] Notably, these codifications are not just a recent phenomenon. South Carolina, for example, adopted a product liability statute in 1962, and Maine followed suit in 1973. See S.C. CODE ANN. § 15-73-10 (Law. Co-op. 1993) (adopted 1962); ME. REV. STAT. ANN. tit. 14, § 221 (West 1980) (adopted 1973). Thus, at the time Congress amended FIFRA in 1972 and 1978, this patchwork was already in existence.

Second, some States that have not enacted comprehensive product liability or tort statutes have nonetheless passed more limited tort reform measures. As a result of such measures, tort claims in these States are based on a hybrid of common law and positive law. Indeed, Texas is a prime example. See TEX. CIV. PRAC. & REM. CODE § 82.001 *et seq.* (Vernon 1997); see generally Comment, *The Products Liability Act of 1993: How It Changes Texas Law*, 45 BAYLOR L. REV. 633, 635 (Summer 1993) ("Though hardly an 'overhaul' of products liability law, the Act must * * * be examined and its effect on the common law determined."). Thus, Texas has prescribed *by statute* the standards that must be satisfied in any product liability action alleging a design defect. TEX. CIV. PRAC. & REM. CODE § 82.005 (Vernon 1997). Given the hybrid nature of tort claims in jurisdictions such as Texas, it would be utterly unmanageable – and require a time-consuming predicate inquiry into state tort law – for preemption to turn on whether a tort-based requirement is rooted in a statute as opposed to the common law.

Third, the common law of many States originated in early *statutes* or *constitutional provisions* adopting the English common law wholesale as the law of the State. For example, "[i]n 1819, the territorial legislature of Florida adopted a statute declaring the common law of England to be of force in Florida. The statute, in modified form but unchanged as to substance, is still in effect * * * ." *Coastal Petroleum Co.* v. *American Cyanamid Co.*, 492 So. 2d 339, 347 (Fla. 1986) (Boyd, J., dissenting) (discussing FLA. STAT. ANN. § 2.01 (1985)), cert. denied, 479 U.S. 1065 (1987). The same is true of many other States – including Texas. *State Farm Fire & Casualty Co.* v. *Gandy*, 925 S.W.2d 696, 706 (Tex. 1996) (explaining that on January 20, 1840, "the Congress of the Republic of Texas adopted the common law") (citing TEX. CIV. PRAC. & REM. CODE § 5.001) (Vernon 2002).[10] Since state common-law

[10] See also MD. CONST. art. 5; ALA. CODE § 1-3-1 (1977); CAL. CIVIL CODE § 22.2; COLO. REV. STAT. ANN. § 2-4-211; see generally Bradley & Goldsmith, *Customary International Law As Federal Common Law: A Critique of the Modern Position*, 110 HARV. L. REV. 815, 870 n.345 (1997) ("[M]ost states have receiving statutes that incorporate as rules of decision at least part of the common law of England."); Note, *English Common Law and Indiana Jurisprudence*, 30 IND. L. REV. 409, 409-10 & nn.2-4 (1997) (discussing and citing many such "reception" statutes).

doctrines evolved from these early English sources, whose legitimacy and force are in turn contingent upon provisions of state positive law, it makes little sense to treat common-law requirements as qualitatively different from statutes.

Fourth, reliance on a distinction between common-law and statutory requirements is especially odd in the area of tort law, where "[c]ompendia such as the torts Restatements help to blur the line between statutes and case law." Bernstein, *The New-Tort Centrifuge*, 49 DEPAUL L. REV. 413, 426 (1999). As Professor Bernstein has correctly explained:

> The traditional Restatement mission was to extract a code of blackletter out of case law, relying mostly on judges' *ratios decidendi* but adding a dose of improvement. The apparatus first makes codification out of case holdings and then cycles back to influence the outcome of case holdings with codification. As if this mechanism were not a sufficient muddying of the distinction between statutes and case law, the Third Restatement chose, for the first time, to "restate" statutes as well as case holdings; in Comments to the products liability blackletter, the Third Restatement relies in part on tort reform statutes to support its claim of a trend or direction in the courts.

Ibid. For this reason as well, it makes no sense to read into Section 136v(b) an exception for state requirements that happen to be rooted in the common law.

II. FIFRA PREEMPTS STATE REQUIREMENTS EVEN IN THE ABSENCE OF A COUNTERPART EPA REGULATION

Petitioners also contend that because EPA has declined to regulate product efficacy, FIFRA's preemption clause does not

prevent the States from imposing requirements relating to pesticide labeling in that area. Pet. Br. 29-37. The Fifth Circuit rejected that argument as contrary to FIFRA's language, explaining that a decision by EPA not to regulate would not "alter the plain meaning of § 136v(b) nor avoid preemption of a claim that has the effect of imposing labeling requirements." Pet. App. 14a-15. "FIFRA's text," the court of appeals reasoned, simply "does not define the scope of FIFRA's preemption clause to be a function of existing EPA regulations." Pet. App. 13a. Thus, even in the absence of labeling requirements imposed by EPA, state requirements are preempted because they "would clearly be * * * 'in addition to or different from those' required under FIFRA." Pet. App. 15a.

Here again, the Fifth Circuit read the statute correctly: Nothing in the text of Section 136v(b) conditions preemption of state-law requirements on the existence of an EPA regulation on the same subject matter.[11] Petitioners' contrary argument fails for multiple reasons. First, Section 136v(b) preempts *any* requirement for labeling or packaging – no distinction is made between requirements (like efficacy) for which the EPA can waive testing, and requirements for which it cannot. Moreover, Congress knows how to make preemption turn on whether an agency has acted by imposing requirements governing the same subject matter or risk. The lack of any such language in FIFRA speaks volumes. Finally, FIFRA preempts requirements for labeling "in addition to or different from" those imposed under FIFRA. The most natural interpretation of that phrase, we submit, clearly encompasses petitioners' state law claims (even those that allegedly mirror federal requirements). If permitted to proceed, petitioners' claims would impose state "requirements" relating to Strongarm's labeling

[11] As respondent demonstrates (Resp. Br. 8-10), the Fifth Circuit was mistaken to the extent that it assumed (see Pet. App. 14a-15a) that EPA does not regulate the accuracy of labeling statements concerning product efficacy.

that are "in addition to or different from" the requirements imposed by FIFRA itself on the product's labeling.

A. In Contrast To Other Preemption Clauses, Section 136v(b) Does Not Condition Preemption On The Existence Of A Counterpart Federal Regulation

Petitioners point out that, "[i]n 1978, Congress amended FIFRA by conferring on EPA the authority it had requested to waive efficacy requirements" (Pet. Br. 31 (citing 7 U.S.C. § 136a(c)(5)); that the agency has "waived its review of proposed label claims relating to pesticide efficacy" for most products (including Strongarm, the pesticide at issue in this case (*ibid.*)); and that EPA therefore "reviews pesticide labels for the adequacy of claims relating to human health and the natural environment – but *not* for 'target area phytotoxicity'" (*ibid.*). Thus, petitioners reason, "there was no FIFRA or EPA labeling 'requirement' to preempt the farmers' suit." Pet. Br. 33. This argument rests not only on an erroneous factual premise (see note 11, *supra*) but also, as explained below, on a flawed interpretation of Section 136v(b).

Section 136v(b) provides broadly and without qualification that the States "shall not impose or continue in effect *any* requirements for labeling or packaging" that are either "in addition to or different from those required under this subchapter." 7 U.S.C. § 136v(b) (emphasis added). Contrary to petitioners' suggestion, Congress's decision to amend FIFRA in 1978 (six years after the preemption provision was enacted) by adding language in Section 136a(c)(5) authorizing the EPA to "waive data requirements pertaining to efficacy" did not engraft an exception on Section 136v(b). See *Etcheverry* v. *Tri-Ag Servs., Inc.*, 993 P.2d 366, 375-76 (Cal. 2000). In fact, Section 136a(c)(5) says nothing at all about preemption; it concerns instead which pesticides may be "register[ed]" by the EPA. Nor is there evidence that Congress intended, in amending FIFRA by adding the pertinent language of Section 136a(c)(5), to create an exception to express preemption. In

short, there is no basis in the text or legislative history of the statute for the novel theory offered by petitioners.

Moreover, Congress knows full well how to specify that a federal requirement on the same subject matter must be in existence before state law is expressly preempted – and has done so in many other preemption clauses. For example, the preemption clause of the National Traffic and Motor Vehicle Safety Act provides:

> *When a motor vehicle safety standard is in effect* under this chapter, a State or a political subdivision of a State may prescribe or continue in effect a standard *applicable to the same aspect of performance* of a motor vehicle or motor vehicle equipment only if the standard is identical to the standard prescribed under this chapter.

49 U.S.C. § 30103(b) (emphasis added). Other examples abound. See, *e.g.*, Radiation Control for Health and Safety Act, 21 U.S.C. § 360ss ("*Whenever any [federal] standard* prescribed * * * with respect to an aspect of performance of an electronic product *is in effect*, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, any standard *which is applicable to the same aspect of performance* of such product and which is not identical to the Federal Standard.") (emphasis added); accord Flammable Fabrics Act, 15 U.S.C. § 1203(a); Consumer Product Safety Act, 15 U.S.C. § 2075(a); National Manufactured Housing Construction and Safety Standards Act of 1974, 42 U.S.C. § 5403(d).[12] Given the frequency with which Congress expressly conditions preemption on the existence of a counterpart federal standard, the absence of similar language in Section 136v(b) goes far toward refuting petitioners' reading.

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[12] See also 49 U.S.C. § 20106 (state may adopt a regulation "until the Secretary of Transportation prescribes a regulation"); 15 U.S.C. § 2617 ("If the Administrator requires by a rule * * * the testing of a chemical substance or mixture, no State * * * may continue [testing] * * * for purposes similar to those for which testing is required under such rule.").

Notably, Congress also knows how to carve out *exceptions* to express preemption commands, and has done so in many other statutes (but again, not in FIFRA). For example, the preemption clause of the Boat Safety Act contains an "except[ion]" allowing States to "regulate the carrying or use of marine safety articles to meet uniquely hazardous conditions or circumstances within the State" in the absence of "disapproval" by the federal government. 46 U.S.C. § 4306. Similarly, Congress included in the express preemption provision of the Flammable Fabrics Act, 15 U.S.C. § 1203(b), an exception for state flammability standards that "afford a higher degree of protection" than do the federal standards. Such exceptions are quite common. *E.g.*, 15 U.S.C. § 1476(b); *id.* § 6715; 49 U.S.C. § 20106. FIFRA includes no exception for situations where the EPA has waived requirements or declined to issue a regulation governing the same subject matter.

Nor does FIFRA's preemption clause grant EPA any authority to *exempt* state labeling requirements from preemption. Significantly, Congress *has* granted other agencies exemption authority under other preemption schemes. See, *e.g.*, 15 U.S.C. § 1203(c) (granting Consumer Product Safety Commission authority under certain circumstances to exempt state requirements from preemption under the Flammable Fabrics Act); *id.* § 1476(c) (same under the Consumer Product Safety Act); accord 21 U.S.C. § 360k(b); 46 U.S.C. §§ 4305, 4306; 15 U.S.C. § 2617(b). And, of course, unlike many other preemption clauses, FIFRA includes no "savings" clause. These contrasting statutory provisions confirm the plain meaning of Section 136v(b) as preempting state labeling requirements even when no counterpart federal regulation exists.

B. The State Requirements Underlying Petitioners' Claims Are "In Addition To Or Different From" The Requirements Imposed By FIFRA Itself

Petitioners appear to believe that Section 136v(b)'s reference to "different" or "addition[al]" requirements supports their argument that express preemption depends on the existence of

a counterpart federal requirement. In fact, that phrase refutes petitioners' reading.

Section 136v(b) preempts "any" state requirements relating to labeling or packaging that are "in addition to or different from those required under this subchapter." 7 U.S.C. § 136v(b). As respondent demonstrates (see Resp. Br. 7-10, 31-32), FIFRA imposes a wide array of requirements on pesticide labeling (as do the EPA's regulations). Moreover, it is undisputed that *FIFRA itself* imposes certain requirements on Strongarm's labeling. See 7 U.S.C. §§ 136j(a)(1), 136(q). At a minimum, the requirements imposed by petitioners' claims are "in addition to or different from" these statutorily imposed requirements. They are also "in addition to or different from" a variety of requirements imposed by EPA's regulations.

Section 136v(b)'s reference to "different" state requirements easily encompasses two situations. First, it encompasses all state requirements as to which federal requirements on the same subject matter exist, but the content of the state and federal duties or obligations differs. To take a concrete example, EPA's imposition of a requirement concerning the wording and coloring of a particular hazard warning would preempt a state labeling requirement that the wording and coloring be different. Second, and fatally for petitioners' "counterpart federal requirement" argument, the word "different" also encompasses all state requirements that relate to *different subject matters* than those covered by existing federal requirements (whether based in FIFRA itself or in the EPA's regulations). Thus, in the example just given of EPA's imposition of a requirement concerning the wording and coloring of a particular hazard warning, Section 136v(b) would preempt a state labeling requirement mandating a particular organization of the labeling. Significantly, the state requirement in this example would be preempted as "different" even in the *absence* of a federal requirement relating to the organization of the product labeling. In both of these situations, the state requirements would be "different" from the federal requirements under the ordinary meaning of that term.

What then does "in addition to" mean? Congress did not say that only state requirements that are "different from" federal requirements are preempted; it said that requirements are preempted if they are either "different from" *or "in addition to"* federal requirements. That language cannot be surplusage. See, *e.g.*, *Doe* v. *Chao*, 124 S. Ct. 1204, 1214 (2004) (quoting *TRW Inc.* v. *Andrews*, 534 U.S. 19, 31 (2001)) ("It is a cardinal principle of statutory construction that * * * no clause, sentence, or word shall be superfluous, void, or insignificant.").

The only independent meaning that "in addition to" can have in the example given above is "identical to." It cannot signify a state requirement that deals with the same subject matter as an existing federal labeling requirement but that differs in the content of the obligations it imposes, because that is already captured by "different." A state requirement that warnings be printed in red is "different" from a federal requirement that they be printed in blue. And it cannot signify state requirements that deal with subjects as to which no federal requirements are in place. That, too, is a "different" state requirement. All that remains are situations where the state and federal requirements cover the same subject matter *and* are identical in content.[13]

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[13] Nothing in *Medtronic* is to the contrary. Although the preemption clause in the MDA contains the phrase "different from or in addition to," 21 U.S.C. § 360k(a), it is triggered only where a federal requirement is "applicable" to the device in question, and (consistent with that language) all parties agreed in *Medtronic* that preemption was triggered under the MDA *only* when a counterpart federal requirement is in place. More importantly, this Court's conclusion in *Medtronic* that "different from or in addition to" did not cover identical state requirements hinged on an FDA interpretation to that effect. See *Medtronic*, 518 U.S. at 495-96; 21 C.F.R. § 808.1(d)(2). Thus, the Court had no occasion in *Medtronic* to conduct an independent analysis of the phrase "different from or in addition to," much less to examine its meaning in the quite different context of a preemption clause such as FIFRA's. See also *United States* v. *Locke*, 529 U.S. 89, 115 (2000) (rejecting argument for exception to preemption on ground that "state rules supplement, or even mirror, federal requirements").

This interpretation is consistent with the ordinary meaning of "in addition to." State law that imposes requirements that parallel federal requirements plainly "add" to the federal obligations. If the EPA forbids misbranding and so does a State, the state requirement is "in addition to" the federal requirement even if it simply imposes another layer of legal obligations.

Finally, this common-sense reading of Section 136v(b)'s language is confirmed by several other express preemption clauses that nullify state requirements that are "different from" or "in addition to" federal requirements – but make an exception for state requirements that are "consistent" with the federal standards. See 21 U.S.C. §§ 678, 1052(a). If "different from or in addition to" already excluded identical requirements, there would have been no need for Congress to include such an exception. Thus, Congress knows how to exclude "identical" state requirements from an express preemption command, and has not done so in Section 136v(b). See also page 26, *supra*. Accordingly, petitioners' labeling-related claims are expressly preempted even if they parallel the federal requirements.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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DENNIS BATES, ET AL.,

Petitioners,

v.

DOW AGROSCIENCES, LLC,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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BRIEF OF CROPLIFE AMERICA AND NATIONAL PEST MANAGEMENT ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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INTEREST OF THE *AMICI CURIAE*[1]

Amici curiae **CropLife America** and **National Pest Management Association** have a substantial interest in the subject of this appeal—the preemptive reach of § 136v(b) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y. The members of these nationally prominent trade associations are the types of companies (pesticide manufacturers, formulators, and distributors, and structural pest control firms) that most frequently are subjected to agricultural crop damage, homeowner property damage, and personal injury suits involving the use of pesticides. The associations are submitting this *amicus curiae* brief for three principal reasons:

(i) To rebut Petitioners' insinuations that affirming the Fifth Circuit's opinion below somehow would shield agricultural pesticide manufacturers from all state law damages remedies for pesticide-related crop injury, and leave aggrieved farmers with no means of obtaining compensation;

(ii) To explain why federal preemption of failure-to-warn and other *labeling*-related damages claims promotes FIFRA's goals and is essential for maintaining the important health, safety, environmental, and product performance benefits provided by nationally uniform pesticide product labeling that is regulated solely by the United States Environmental Protection Agency (EPA); and

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[1] The parties have lodged with the Clerk blanket consents to the filing of *amicus curiae* briefs. Pursuant to Sup. Ct. R. 37.6, *amici curiae* CropLife America and National Pest Management Association state that no counsel for a party has written this brief in whole or in part, and that no person or entity, other than *amici curiae*, its members, or its counsel, has made a monetary contribution to the preparation or submission of this brief.

(iii) To highlight the implausibility of Petitioners' contention that by enacting FIFRA's so-called efficacy data waiver, Congress intended to create a gaping exception to preemption for labeling-related damages claims that involve agricultural crop injury.

CropLife America, a national, not-for-profit trade association, represents the American plant science industry on a broad range of legislative, regulatory, legal, scientific, and product stewardship issues. Its members serve farmers and consumers by developing, manufacturing, and distributing virtually all of the agricultural crop protection pesticides and biotechnology products used to produce safe, high-quality, affordable, and abundant food, fiber, and other crops.

For the past 57 years, CropLife America (formerly known as the American Crop Protection Association, and before that, the National Agricultural Chemicals Association) has been industry's foremost voice on enactment, amendment, and implementation of FIFRA, the nation's primary pesticide regulatory statute. CropLife America and its members consider FIFRA's carefully balanced allocation of pesticide regulatory authority between EPA and the states, especially the system of federally regulated, nationally uniform product labeling mandated by § 136v(b), to be a subject of paramount importance. For this reason, CropLife America has an abiding interest in ensuring that courts, when confronted with state law liability claims that directly or indirectly attack the adequacy of the warnings, precautionary measures, directions for use, or other information on a pesticide's federally regulated product labeling, properly apply § 136v(b), which expressly preempts the states from imposing "any requirements for labeling" that are "in addition to or different from" those imposed under FIFRA. 7 U.S.C. § 136v(b).

On numerous occasions during the past 12 years, CropLife America has successfully argued in *amicus curiae* briefs submitted to federal courts of appeals and state appellate

courts that § 136v(b) encompasses requirements imposed through state damages claims for inadequate labeling or failure to warn. In addition, last year CropLife America filed an *amicus curiae* brief urging review of the Texas Supreme Court's opinion in *American Cyanamid Co. v. Geye*, 79 S.W.3d 21 (Tex. 2002), *cert. denied*, 539 U.S. 969 (2003), which contrary to the Fifth Circuit's opinion here, erroneously held that all agricultural crop damage claims (including those that are labeling-related) are excluded from preemption.

The **National Pest Management Association** ("NPMA") is a national, not-for-profit, trade association representing more than 5,000 pest control companies throughout the United States. The association's members help protect food, health, property and the environment with a broad range of pest management services such as control of termites, insects, and rodents in residential, commercial, and institutional settings; control of mosquitoes and wildlife that transmit West Nile Virus or other life-threatening diseases; and control of stored product pests in food handling and agricultural surroundings. NPMA, which was established in 1933, supports its members through technical, educational, business, public relations, and government affairs programs. Since pest management professionals are both required and trained to apply pesticides in a manner consistent with their nationally uniform, EPA-approved product labeling, NPMA participates as *amicus curiae* in appeals involving important issues arising under FIFRA, including the statute's preemptive effect. For example, NPMA and other associations (including CropLife America) jointly filed an *amicus curiae* brief in *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597 (1991) (involving FIFRA preemption of a local government pesticide use ordinance), in which the Court confirmed (*id.* at 615) that "labeling . . . fall[s] within an area that FIFRA's 'program' pre-empts." NPMA has

joined CropLife America here because the categorical anti-preemption position that Petitioners and most of their *amici* are advocating would severely undermine the congressionally mandated system of nationally uniform pesticide product labeling, which greatly facilitates applicator training and safety, and helps to protect consumers and the public.

SUMMARY OF ARGUMENT

The scope of FIFRA's express preemption provision, § 136v(b), is defined by its own plain, broad, language. States are unequivocally prohibited from imposing "any requirements for *labeling*" which are "in addition to or different from" those required under FIFRA. 7 U.S.C. § 136v(b) ("Uniformity") (emphasis added). This Court's preemption jurisprudence establishes that a federal statutory prohibition against imposition of state requirements easily encompasses requirements imposed through state damages actions. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992); *see also Medtronic v. Lohr*, 518 U.S. 470, 504, 509 (1996); *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993). Therefore, as numerous federal courts of appeals and state appellate courts have held, § 136v(b) expressly preempts any state damages claim, such as a claim based on failure to warn, that would have the effect of imposing state requirements for labeling which are in addition to or different from those that have been imposed under FIFRA. The same courts have been equally clear, however, that § 136v(b) does not preempt non-labeling related claims. Petitioners' overblown assertions implying that § 136v(b) immunizes pesticide manufacturers from all "damages actions" (rather than merely preempting labeling-related claims), and leaves farmers with no means of obtaining compensation for crop injury, are unfounded both as a matter of law and fact. Pesticide manufacturers are excellent product stewards, and have strong economic incentives for resolving crop injury problems before they turn into litigation. This is why crop damage litigation is the exception, not the norm.

Nationally uniform product labeling that is regulated solely by EPA plays a critical role in achieving FIFRA's fundamental goal of protecting health and the environment. For example, such labeling is an essential component of educational and training programs for pesticide applicators, and enormously aids applicator comprehension of, and compliance with, label warnings, precautionary measures, and directions for use. Only EPA (and certainly not a lay juror) has the expertise, experience, and other resources to determine, on a product-by-product, category-by-category, or across-the-board basis, what specific warnings, precautionary measures, and other information should or should not be included on nationally uniform pesticide labeling. Rather than having a salutary effect, the nationwide epidemic of labeling-related damages suits that Petitioners and their *amici* are urging this Court to trigger would clash with FIFRA's health and environmental goals by drastically undermining the integrity of EPA's labeling determinations, and for all practical purposes, destroying national labeling uniformity.

Section 136v(b), enacted in 1972, contains no exception to preemption for labeling-related damages claims that involve agricultural crop injury. Nor did Congress intend to amend § 136v(b), or otherwise affect that provision's self-executing operation, when in 1978 at EPA's request, it streamlined FIFRA's federal registration procedures, including by enacting the efficacy data waiver authorization found in § 136a(c)(5). Congress authorized EPA to selectively waive submission of efficacy data to support a registration because of the high level of efficacy-related expertise within the agricultural community, *not* the courtroom. Lay juries would not have the type of expertise that Congress had in mind if called upon in a crop injury suit to second-guess the adequacy of EPA's labeling determinations.

ARGUMENT

I. SECTION 136v(b) OF FIFRA NEITHER PREEMPTS ALL DAMAGES CLAIMS AGAINST PESTICIDE MANUFACTURERS NOR PRECLUDES FARMERS FROM OBTAINING COMPENSATION FOR CROP INJURY

A. The Lower Courts Have Consistently Held That Only *Labeling*-Related Damages Claims Are Preempted By § 136v(b)

By its own express terms, § 136v(b) of FIFRA is limited to preemption of "any requirements for *labeling* . . . in addition to or different from those required under [the Act]." 7 U.S.C. § 136v(b) (emphasis added). As a result, only *labeling*-related damages claims, such as failure-to-warn claims (which necessarily impose state law requirements for "adequate" label warnings), are expressly preempted. This is the fixed, statutorily defined scope of tort preemption under § 136v(b). Nevertheless, in an effort to bolster their extreme position that § 136v(b) does not preempt *any* damages claims, Petitioners, in the first 29 pages of their brief, attempt to transform FIFRA preemption into an all-or-nothing proposition. They erect and then take aim at an easy but illusory target, namely that Congress did not intend § 136v(b) to immunize pesticide manufacturers from all state law liability or deprive farmers of all state law damages remedies. *See, e.g.*, Pet. Br. at 2 ("it is unthinkable that Congress . . . intended to exonerate manufacturers from traditional state-law remedies"); at 14 ("State damages actions are not preempted by FIFRA"); at 16 ("Nothing . . . indicates that Congress intended to . . . preclud[e] farmers from seeking redress for the damages caused to them by pesticide manufacturers."); at 25 ("FIFRA's Legislative History And Purposes Reveal No Intent To Preempt Damages Actions"); at 26 ("no witness or Member of Congress ever suggested that the proposed [1972] legislation would shield pesticide manufacturers from product

liability tort suits"); at 29 ("it does not follow that *all* such claims are barred").

Unlike virtually every lower court that has opined on the scope of FIFRA tort preemption, Petitioners and their *amici* somehow overlook the clearly circumscribed preemptive boundary of § 136v(b) (*i.e.*, preemption of additional or different requirements for *labeling*) and that provision's resultant limitation to *labeling*-related damages claims, such as claims for failure to warn.[2] To be sure, "[t]he federal court decisions holding that FIFRA preempts state law failure-to-warn claims are numerous, consistent, pragmatic and powerfully reasoned." *Etcheverry v. Tri-Ag Service, Inc.*, 993 P.2d 366, 368 (Cal. 2000).[3] But as the Fifth Circuit reconfirmed in its opinion below, "FIFRA does not preempt common law that is unconcerned with [pesticide] labeling." Pet. App. 10a (citing *Andrus v. AgrEvo USA Co.*, 178 F.3d 395, 398 (5th Cir. 1999)); *see also id.* at 11a (quoting *Hart v. Bayer Corp.*, 199 F.3d 239, 245 (5th Cir. 2000) ("FIFRA preemption does not extend to non-labeling state common-law causes of action"). Indeed, "courts have rejected preemption challenges with regard to a wide variety of claims where they did

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[2] Section 136v(b) also preempts "any requirements for . . . packaging in addition to or different from those required under [FIFRA]." Nothing in this brief is intended to imply that § 136v(b) does not also encompass packaging-related claims.

[3] The California Supreme Court squarely rejected all of the arguments, many of which are repeated by Petitioners here, in what Petitioners nevertheless describe as the "powerful brief" (Pet. Br. at 28) filed by the government as *amicus curiae* in *Etcheverry*. *See Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1207 (9th Cir. 2002) ("The California Supreme Court found the EPA's position [in *Etcheverry*] both unsupported by the relevant law and unpersuasive in its substance, noting that the EPA's views went against the holdings of eight federal circuit courts of appeal."). Last term the government advised this Court that it has "reexamined the position that it urged in *Etcheverry* [and] concluded that [it] is incorrect." U.S. Br. at 17, *American Cyanamid Co. v. Geye* (No. 02-367).

not implicate requirements for labeling." *Etcheverry*, 993 P.2d at 377 (collecting cases).

For example, in *Netland v. Hess & Clark, Inc.*, 284 F.3d 895, 900 (8th Cir.), *cert. denied*, 537 U.S. 949 (2002), the court of appeals reaffirmed that " 'if the state law claim is *premised* on inadequate labeling or a failure to warn,' which results in the imposition of additional or different labeling requirements, the claim is nonetheless preempted regardless of the guise under which the claim is presented" (quoting *Nat'l Bank of Commerce v. Dow Chem. Co.*, 165 F.3d 602, 608 (8th Cir. 1999)); *see, e.g., Grenier v. Vermont Log Bldgs., Inc.*, 96 F.3d 559, 565 (1st Cir. 1996) (§ 136v(b) preempts a purported design or manufacturing defect claim if it actually is a "disguised labeling claim"). But "[t]he line between a claim for mislabeling and a claim for a defective product may not always be clear." *Worm v. American Cyanamid Co.*, 5 F.3d 744, 747 (4th Cir. 1993). The court of appeals agreed with the plaintiff in *Netland* "that defectively manufactured or designed products properly labeled under FIFRA remain subject to state regulation, in the form of common law or other claims." 284 F.3d at 900. Thus, § 136v(b) would not preempt a farmer's claim that his crops were destroyed by a herbicide which, due to a manufacturing error, contained substantially more active ingredient than allowed by its FIFRA registration. Nor would § 136v(b) preempt a claim that a herbicide was ineffective in killing weeds because it contained substantially less active ingredient than approved by EPA. Along the same lines, a claim that "particular lots" of herbicide caused crop damage because they were "negligently contaminated" with another herbicide has been held not preempted. *In re DuPont-Benlate Litigation*, 859 F.Supp 619, 622, 623 (D.P.R. 1994); *see also Nat'l Bank of Comm.*, 165 F.3d at 608-09 (§ 136v(b) does not preempt a claim based on the presence of a "toxic impurity" in a pesticide product). And a district court recently ruled

that § 136v(b) does not preempt a negligent distribution claim alleging that a bulk container of an agricultural pesticide "erupted" and caused environmental contamination. *See Akee v. Dow Chem. Co.*, 272 F.Supp.2d 1112, 1127 (D. Hawaii 2003) ("the court does not see anything in the record before it suggesting that this claim is in any way a labeling or warning based claim").

The lower courts have been virtually unanimous in holding that "[w]hen a claim, however couched, boils down to an assertion that a pesticide's label failed to warn of the damage plaintiff allegedly suffered, the claim is preempted by FIFRA." *Etcheverry*, 993 P.2d at 376 (collecting cases). For example, § 136v(b) preempts claims alleging that a pesticide is "misbranded" (which § 2(q)(1)(G) defines to include labels that do not contain adequate warnings). *See, e.g., Kuiper v. American Cyanamid Co.*, 131 F.3d 656, 666 (7th Cir. 1997); *Papas v. Upjohn Co.*, 985 F.2d 516, 518-19 (11th Cir. 1993). But a claim alleging that the manufacturer of corn seed which was genetically modified to be resistant to certain insects failed to comply with the terms of a FIFRA conditional registration, such as selling the seeds without the label required by EPA, has been held not to impose an additional or different requirement for labeling, and thus, not preempted. *See In re Starlink Corn Products Liability Litigation*, 212 F.Supp.2d 828, 836 (N.D. Ill. 2002).

Further, the lower courts have consistently held that § 136v(b) preempts claims for misrepresentation or breach of express warranty based on so-called "off-label" statements (*e.g.*, advertising statements; oral statements) "if they merely repeat information in the label itself." *Kuiper*, 131 F.3d at 662; *see also* Pet. App. 17a (farmers' fraud and breach of warranty claims are preempted "[b]ecause no evidence was presented demonstrating that the retailer statements deviated from the contents of the Scepter label"); *Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555, 563 (9th Cir. 1995) (FIFRA

preempts claim based on distributor's oral representation regarding crop safety where there was "no evidence establishing that [it] made any statements that were inconsistent with or went beyond the labels"); *Lowe v. Sporicidin Int'l*, 47 F.3d 124, 127-30 (4th Cir. 1995) (§ 136v(b) preempts claims based on "off-label" representations which do not "substantially differ" from the label). As the California Supreme Court indicated in *Etcheverry*, however, "[w]here off-label statements address matters outside the scope of the label, an action may well lie." 993 P.2d at 378; *see, e.g., In re Starlink*, 212 F.Supp.2d at 836-37 ("Claims based on off-label representations . . . are not preempted . . . to the extent the representations substantially differ from the label."); *id.* at 837 (holding that oral statements to farmers that genetically modified corn "was safe for human consumption . . . directly contradict the approved label"). Thus, if a herbicide were registered only for use on peanuts, but the manufacturer advertised that it also works well on cotton, § 136v(b) would not preempt a cotton crop injury claim based on that off-label statement, since it substantially differs from, rather than repeats the information on, the EPA-approved label.

Therefore, affirming the principle adopted by numerous federal and state appellate courts that § 136v(b) preempts only failure-to-warn and other labeling-related claims would *not*, as Petitioners claim, give "sweeping effect to the preemption provision." Pet. Br. at 1. Preemption of such claims benefits farmers and the public by preserving the national labeling uniformity mandated by Congress (see discussion *infra*), but contrary to the hyperbolic advocacy of Petitioners and their *amici*, in no way precludes farmers or other plaintiffs from pursuing non-labeling related damages actions against pesticide manufacturers. *See Lescs v. William R. Hughes, Inc.*, 168 F.3d 482 (Table), No. 97-2278, 1999 WL 12913, at *7 (4th Cir. Jan. 14, 1999) (Text) ("FIFRA's language does not suggest some extraordinarily broad scope

of preemption that extends beyond the statutory scheme. Nor does it work to destroy all means of redress for plaintiffs under the common law of a state.").

B. Agricultural Pesticide Manufacturers Are Conscientious Product Stewards Which Strive To Maintain Good Will With Farmers Through Prompt Resolution Of Crop Injury Claims

According to Petitioners, "[b]ecause nothing in FIFRA affords compensation to parties injured by pesticides, state-law damages claims properly fill the void left by Congress." Pet. Br. at 14. This facile logic erroneously implies that litigation is the only way that farmers can obtain compensation from pesticide manufacturers for crop injury. Like most farmers, these Petitioners, to whom Respondent offered the opportunity to obtain reasonable compensation without litigation (*see* J.A. 143-45), know better.

In reality, pesticide manufacturers are an integral, well respected part of the agricultural community. Along with university researchers, agricultural extension agents, private crop consultants, seed suppliers, farm store retailers, and custom applicators, pesticide manufacturers and their distributors serve as an important informational resource to farmers. For example, manufacturers provide farmers, either directly or through distributors and retailers, with abundant technical information regarding their products and how they can be used safely and effectively on particular crops. In addition, manufacturers continually interact with farmers to better learn how their products perform in specific geographic locations or under particular environmental conditions. Such information can lead to more finely tuned directions for use, and when necessary, use restrictions.

Moreover, R&D-oriented pesticide innovators invest hundreds of millions of dollars in screening, testing, and registering highly efficacious new products that benefit farmers, the

agricultural economy, and consumers throughout the United States and world. These include, for example, low dose, less toxic products which break down rapidly after application to food crops; products applied with advanced delivery systems that reduce applicator and environmental exposure; and biotechnology products, such as genetically engineered seed that grows into insect-resistant crops. Prior to obtaining a FIFRA registration for a new agricultural pesticide, a manufacturer may conduct more than 250 health, safety, environmental, and efficacy studies. In addition to their individual activities, pesticide manufacturers, through CropLife America, participate in industry-wide product stewardship programs, such as the Ag Container Recycling Council, which helps farmers reduce disposal costs and avoid environmental contamination.

Petitioners' contention that a multitude of lay jurors, who know nothing about crop production or pesticides, should have free reign to find that pesticide manufacturers' EPA-approved labeling is inadequate, and on that basis, render huge damages awards in order to fill a FIFRA compensation "void," fails to take into account the highly collegial and cooperative relationship between agricultural pesticide manufacturers and farmers. As a matter of good product stewardship and sound business sense, manufacturers' regional and local field representatives, who typically have considerable agronomic expertise, work closely with farmers to promptly investigate and resolve product performance and/or crop injury problems without litigation. Most pesticide manufacturers have well established customer satisfaction policies. When circumstances warrant, and depending on the nature of the problem, remedies provided by manufacturers may range from re-application of pesticides at the manufacturer's expense, to reimbursement of the cost of unsatisfactorily performing products, to replacement of seed or monetary compensation for injured crops. Upon the infrequent event of widespread crop injury problems with a product, manu-

facturers have established formal claims settlement procedures (such as the Strongarm mediation program initiated by Respondent here) in order to maintain the company's reputation and good will, treat farmers fairly, and avoid lawsuits.

If FIFRA tort preemption were the all-encompassing product liability defense that Petitioners and their *amici* pretend to fear, manufacturers, aside from their excellent product stewardship and strong economic incentives for satisfying farmers' needs, would have little reason to resolve crop injury claims. Instead, manufacturers invest substantial financial resources to resolve any crop injury problems that farmers encounter. As a result, and contrary to the impression that Petitioners try to create, the need to file crop damage suits for the purpose of obtaining compensation from pesticide manufacturers is the exception, and certainly not, as Petitioners assert, a reason to hold that § 136v(b) is limited to positive enactments.

II. FIFRA PREEMPTION OF LABELING-RELATED DAMAGES CLAIMS PRESERVES THE SIGNIFICANT HEALTH, SAFETY, ENVIRONMENTAL, AND PRODUCT PERFORMANCE BENEFITS OF EPA-REGULATED, NATIONALLY UNIFORM PRODUCT LABELING

A. Nationally Uniform Product Labeling Plays A Crucial Role In The Coordinated Federal/State Regulatory Partnership Established By Congress

"FIFRA's historic focus [is] on labeling." *Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. at 613. When FIFRA was first enacted in 1947, it was intended to supplement existing regulation of pesticides by the states. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 990 n.2 (1984); *National Agric. Chem. Ass'n v. Rominger*, 500 F. Supp. 465, 468 (E.D. Cal.

1980). But even back then, Congress was concerned about the need for promoting national uniformity in pesticide labeling. *See* H.R. Rep. No. 313, at 3 (1947) (noting that the 1947 FIFRA "is in accord" with the Uniform State Insecticide, Fungicide, and Rodenticide Act; that enactment of the federal legislation "will greatly facilitate the coordination of work in this field among the States and with the Federal Government;" and that "[i]t is highly desirable that laws governing [pesticides] be as nearly uniform as possible . . . so that manufacturers may have Nation-wide distribution with a *minimum of conflict between the labeling requirements* of the various laws.") (emphasis added). To this end, "[t]he 1947 legislation . . . contained general standards setting forth the types of information necessary for proper labeling of a registered pesticide, including directions for use; warnings to prevent harm to people, animals, and plants; and claims made about the efficacy of the product." *Ruckelshaus*, 467 U.S. at 991. There was, however, no express preemption provision regarding state regulation of labeling.

"In 1972, growing environmental and safety concerns led Congress to undertake a comprehensive revision of FIFRA." *Mortier*, 501 U.S. at 601. Congress transformed the Act into a "comprehensive regulatory statute" (*Ruckelshaus*, 467 U.S. at 991) and "significantly strengthened [its] registration and labeling standards." *Mortier*, 501 U.S. at 601. During its extensive deliberations, Congress carefully considered the allocation of pesticide regulatory authority between the newly created EPA and the states in order to establish "a coordinated Federal-State administrative system to carry out the new program." *Id.* at 615 (quoting H.R. Rep. No. 92-511, at 1). Under that "regulatory partnership" the states share responsibility with EPA for regulating the sale and use of pesticides, but pesticide "labeling . . . fall[s] within an area that FIFRA's 'program' pre-empts." *Id.*; *see also New York State Pesticide Coalition v. Jorling*, 874 F.2d 115, 118 (2d

Cir. 1989) ("The states have joint control with the federal government in regulating the use of pesticides . . . with the exception of the EPA's exclusive supervision of labeling.").

More specifically, the 1972 FIFRA amendments added § 136v(b) ("Uniformity"), which Congress intended "to completely preempt State authority in regard to labeling." H.R. Rep. No. 92-511, at 16 (1971). Representatives of both the pesticide industry and agriculture testified in support of the need for national labeling uniformity. *See, e.g. Fed. Env. Pesticide Control Act: Hearings Before the Subcomm. on Agric. Research & Gen'l Legis. of the Sen. Comm. on Agric. & Forestry*, 92d Cong. 416 (Mar. 9, 1971) (Stmnt. of Parke C. Brinkley, President, Nat'l Agric. Chem. Ass'n) (EPA has "sufficient scientific expertise [for] the determination of the proper labeling . . . of each product. There is no need for this process to be duplicated in each of the 50 States."); *id.* at 354 (Stmnt. of Clifford G. McIntyre, Director, Natural Resources Dept., and Ass't Legis. Dir., Am. Farm Bureau Fed.) ("In labeling the manufacturers have a real problem with the whole diversified requirements in 48 States. We accept the concept of some uniformity."). EPA and state pesticide regulators also supported national uniformity. *See id.*, 92d Cong. 87 (Mar. 7-8, 1972) (Stmnt. of David D. Dominick, Ass't Admin. for Categorical Programs, EPA) ("I think that the basic thrust that is needed in new legislation is uniformity [of] registration."); *id.* at 153 (Stmnt. of Charles H. Frommer, Dir., Bureau of Pesticide Control, N.Y. State Dep't of Env'l Conservation) ("We very strongly favor the provision of [§ 136(b)] which provides for uniform labeling. We have endorsed uniform labeling and we intend to continue to endorse uniform labeling.").

As the Solicitor General explained to the Court in *Mortier*, "an exclusively federal approach is necessary in certain areas of pesticide regulation. One such area is labeling." U.S. Br. at 22, *Wisconsin Pub. Intervenor v. Mortier* (No. 89-1905).

Thus, as amended, "FIFRA placed the 'labeling' of pesticides within the singular province of the EPA." *Jorling*, 874 F.2d at 117. Indeed, Congress intended a pesticide's nationally uniform, EPA-approved product labeling not to be merely a "guide," but instead, "the final authority" governing application of a pesticide. S. Rep. No. 95-334, at 4 (1977). Further, prior to 1972, FIFRA contained "no prohibition . . . against the misuse of a registered pesticide." S. Rep. No. 92-838, at 4 (1972). In order to correct this deficiency, Congress added § 136j(a)(2)(G), which makes it "unlawful for any person . . . to use any registered pesticide in a manner inconsistent with its labeling." 7 U.S.C. § 136j(a)(2)(G). To underscore the importance of this federal statutory prohibition, EPA requires every pesticide label to caution applicators that "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." 40 C.F.R. § 156.10(i)(2)(ii). In fact, FIFRA's fundamental precept that "The Label Is The Law" is a prominent feature of the basic training provided in virtually every state-sponsored pesticide applicator training program. *See, e.g.*, Northeastern Regional Pesticide Coordinators, *Pesticide Applicator Training Manual* (commonly referred to as the multi-state "*Core Manual*"), Ch. XIV-3 (2d ed., revised 1998).

Pesticide labeling is different from the ordinary labels placed on most types of products. It is the principal means by which EPA ensures that all necessary warnings, safety precautions, personal protective equipment requirements, directions for use, and other essential information is communicated from a pesticide's manufacturer through the chain of distribution to the individuals who actually handle and use the product. *See* 40 C.F.R. Part 156 (Labeling Requirements for Pesticides); *see also Jorling*, 874 F.2d at 119 ("'FIFRA labeling' is designed to be read and followed by the end user."). EPA continually stresses the importance of reading and complying with all pesticide labeling requirements. *See,*

e.g., "Read the Label First" (http://www. epa.gov/pesticides/label). It is difficult to overstate the substantial health, safety, environmental, and product performance benefits that nationally uniform, EPA-regulated product labeling affords to farmers, professional pesticide applicators, and the public:

First, EPA has the necessary personnel, expertise, experience, institutional policies, funding, and national perspective, and possesses (or has access to) the registration data (*e.g.*, product chemistry data; toxicity data; environmental fate data; fish and wildlife data; *and* efficacy data) required to comprehensively regulate the warnings, precautionary measures, directions for use, and other information on a product's labeling before and/or after the product is registered. Needless to say, review and regulation of product labeling is a responsibility which EPA takes very seriously. *See, e.g.*, EPA, *Label Review Manual*, *available at* http://www.epa.gov/oppfead1/labeling/lrmail. No state agency, much less a court or jury, has resources or expertise which approach EPA's capability to scrutinize or regulate pesticide labeling.

Second, distribution of a FIFRA-registered product with its own, EPA-approved, nationally uniform labeling is essential for applying or using it in a safe and effective manner. As part of their product stewardship and marketing activities, manufacturers of agricultural, structural pest control, public health, and other types of pesticides provide written information to farmers, professional applicators, and other users regarding how to apply or use particular products safely and effectively in accordance with their EPA-approved labeling. Manufacturers, often in conjunction with distributors, university and extension personnel, state regulators, and national, state and local trade associations, also conduct educational and training sessions on a local, regional, or national level. *Label review and comprehension is the cornerstone of such programs.* Without nationally uniform labeling for a pesticide product, detailed application information and appro-

priate training would be difficult if not impossible to provide. Further, if pesticide manufacturers were confronted with the economic burden and logistical nightmare of distributing the same product for the same uses with different labeling required by different states (or inexpert juries), they could be forced to make their products available only in the states with the largest potential markets. That would deprive farmers in other states of the beneficial, cost-effective products that they need.

Third, across-the-board national labeling uniformity for all FIFRA-registered products with respect to format (*e.g.*, the listing of active ingredients), and the utilization of toxicity signal words (*e.g.*, "DANGER;" "WARNING") and precautionary statements for physical and chemical hazards (*e.g.*, "Corrosive, causes eye or skin damage;" "Extremely flammable"), facilitates applicator training and label comprehension. *See* 40 C.F.R. Part 156. Uniformity also is critical for first aid and the operations of the National Pesticide Information Center (http://www.npic.orst.edu) and other poison control centers. *See, e.g.*, Pesticide Registration ("PR") Notice 2001-1 ("First Aid Statements on Pesticide Product Labels") (EPA PR notices can be accessed through http://www.epa.gov/PR_Notices).

Fourth, to the extent feasible and appropriate, EPA also strives to achieve labeling uniformity for various categories of products in order to promote their safe and effective use. For example, in April 2004 EPA issued for comment draft uniform labeling statements for professionally applied, wide-area adult mosquito control products. *See* 69 Fed. Reg. 23,200 (Apr. 28, 2004). These labeling requirements, which EPA developed with input from state regulators, set forth certain specific language to be included on the labeling of such products. EPA's "purpose [is] to improve consistency in the labeling of this group of products [to] better serve the needs of users, regulators and the public." Draft PR Notice

2004-XX at 3. Among other things, the draft PR notice includes uniform mosquito product label language "to ensure use or supervision by trained applicators" and "to protect bodies of water and aquatic life." *Id.* at 4, 6. Along the same lines, EPA has adopted uniform requirements for certain aspects of the labeling of other categories of pesticide products. These include flammable total release room foggers, (40 C.F.R. § 156.78(d)), non-antimicrobial residential/household use insecticides (PR Notice 2001-6), insect repellents (PR Notice 2001-3), soil applied termiticides (PR Notice 96-7), and pet care pesticide products (PR Notice 96-6). The purpose of these and similar EPA labeling requirements for categories of products is to "bring uniformity" to pesticide labeling. *See* PR Notice 97-8.

Fifth, there are numerous national and regional structural termite and pest control companies and lawn care companies which apply pesticides in multiple states. Such firms develop and conduct their own extensive technician (*i.e.*, pesticide applicator) training, often with the assistance of product manufacturers and distributors. The same is true for the companies that protect public health through wide-scale mosquito and vector control. Applicator training would be exceedingly difficult to develop and conduct if a particular pesticide product used by a pest control company had different labels (with different warnings, personal protective equipment requirements, directions for use, etc.) in different states. To say the least, such disparate labels would be confusing and difficult to follow for individual pest control technicians, many of whom routinely cross state lines in a day's work.

Sixth, nationally uniform product labeling not only promotes applicator compliance, but also, state enforcement activities. Although § 136v(b) reserves to EPA alone the authority to regulate the content and format of pesticide labeling, Congress has assigned to the states the "primary

enforcement responsibility for pesticide use violations." 7 U.S.C. § 136w-1(a). This means that the states have the principal responsibility for ensuring that pesticides are applied or used in accordance with their nationally uniform labeling. Because of national labeling uniformity, state pesticide enforcement officia are able to interact with each other to address compliance issues relating to particular labeling requirements for specific products or categories of products. For example, the Association of Structural Pest Control Regulatory Officials ("ASPCRO") is a professional association whose members often comment to EPA as a group regarding labeling issues relating to specific termite control and other structural pesticide products. *See* http://www.aspcro.org. Another organization, the Association of American Pesticide Control Officials ("AAPCO") is comprised of state and federal pesticide regulatory officials. AAPCO's primary mission is "to encourage uniformity among the states in their pesticide regulatory programs," such as "uniform and effective . . . enforcement," including with regard to "safe use of pesticides." *See* AAPCO Mission Statement, *available at* http://aapco.ceris.purdue.edu/htm/mission.htm. AAPCO could not fulfill its mission without nationally uniform pesticide labeling.

The foregoing are only some of the reasons why Congress, in enacting § 136v(b), mandated nationally uniform pesticide labeling, which more than ever remains a *crucial* mechanism for achieving FIFRA's goals, especially protection of health and the environment.

B. Labeling-Related Damages Claims Would Impair—Not Promote—FIFRA's Goals

"The objectives and purposes of FIFRA include . . . comprehensive and uniform regulation of . . . labeling." *Worm*, 5 F.3d at 747. According to Petitioners, however, preemption of state damages actions that attack the adequacy of the warnings and other information on EPA-approved, nationally

uniform product labeling somehow conflicts with FIFRA's goals. *See, e.g.*, Pet. Br. at 14 ("To construe § 136v(b) as preempting the farmers' suits would be contrary to Congress's central aim. . . ."). One of the *amicus* briefs filed in support of Petitioners even argues that "FIFRA and state damages actions complement one another in a constructive way." Br. of Natural Resources Defense Council, et al. at 1. But *exactly the opposite* is true. Labeling-related damages claims would seriously undermine EPA's exclusive authority to regulate pesticide labeling, severely thwart national labeling uniformity, and substantially diminish the health, safety, environmental, and product performance benefits that only nationally uniform labeling can provide. Petitioners' argument (Pet. Br. at 25-26) that FIFRA did not preempt failure-to-warn suits *prior* to the pesticide regulatory sea change which Congress effected in 1972—in other words, before Congress' mandate for national labeling uniformity—proves nothing regarding the preemptive purpose, nature, and effect of § 136v(b), or the deleterious effects that labeling-related damages claims would have on the federal pesticide regulatory scheme today.

"[T]he purpose of Congress is the ultimate touchstone of pre-emption analysis." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (internal quotation omitted). Congress' purpose in enacting § 136v(b), which is entitled "Uniformity," is absolutely clear: "In dividing the responsibility between the States and the Federal Government for the management of an effective pesticide program, the Committee has adopted language which is *intended to completely preempt* State authority in regard to labeling. . . ." H.R. Rep. No. 92-511, at 16 (1971) (emphasis added). It is simply *implausible* that Congress, utilizing the broad and unambiguous language of § 136v(b), would have so clearly intended to preempt the states from imposing their own additional or different requirements for labeling, but simultaneously intended to

allow the states, "through the back door by means of tort suits," to impose precisely such additional or different labeling requirements. *Etcheverry*, 993 P.2d at 376.

There can be no doubt that "[t]he effects of . . . the state tort suit are identical" to those of a "state agency regulation." *Medtronic*, 518 U.S. at 504 (Breyer, J., concurring in part and concurring in the judgment); *see also Cipollone*, 505 U.S. at 521 ("The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.") (internal quotation omitted); *Taylor*, 54 F.3d at 560 ("Awarding damages on the Appellants' claim would therefore be tantamount to allowing the state . . . to regulate pesticide labeling indirectly, an action which is specifically prohibited by § 136v(b)."); *Worm v. American Cyanamid Co.*, 970 F.2d 1301, 1307 (4th Cir. 1992) ("surely a jury verdict resulting from a pesticide manufacturer's failure to warn of the dangers of the product has an effect no different from a legislatively enacted state regulation requiring the insertion of a specific warning on the pesticide label"); *see generally* Viet D. Dinh, "Reassessing the Law of Preemption," 88 Geo. L.J. 2085, 2114 (2000) ("the effect of tort liability on primary conduct is the same as a statutory prescription or regulatory standard").

As a result, without preemption of labeling-related damages claims, nationally uniform labeling would become a mockery, or at the very least exceedingly difficult to achieve or maintain. The "undeniable practical effect" of such damages claims "would be that state law *requires* additional labeling standards not mandated by FIFRA; it cannot be presumed that businesses wish to bring about their own economic suicide." *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 (5th Cir. 1994). To avoid state tort liability for inadequate labeling, pesticide manufacturers would be compelled by the vagaries of each adverse jury verdict to seek EPA's permission to add more and more additional,

different, inconsistent and/or conflicting warnings, precautionary measures, directions for use, etc. to their "nationally uniform" labeling. "Such a change, if permitted by the EPA, would destroy the uniformity that Congress and the EPA seeks to achieve in pesticide labeling . . . case-by-case, state-by-state outside pressure on the regulatory process would hinder the development of an orderly, systematic, and uniform nationwide labeling scheme." *Papas v. Upjohn Co.*, 926 F.2d 1019, 1025-26 (11th Cir. 1991).

Furthermore, unlike EPA, common-law juries lack the expertise, experience, resources, and national perspective to review a pesticide's labeling for accuracy and adequacy, much less impose their own additional or different labeling requirements. Nevertheless, Petitioners' proposal to allow individual juries around the nation "to sit, in effect, as super-EPA review boards that could question the adequacy of the EPA's [labeling] determination[s]" would, as a practical matter, destroy national labeling uniformity. *Welchert v. American Cyanamid, Inc.*, 59 F.3d 69, 73 (8th Cir. 1995). More specifically, the resultant jumble of differing or conflicting, jury-imposed warnings, precautionary measures, directions for use, etc. would compel manufacturers to try to devise "patchwork" labeling, which if approved by EPA, would be lengthy, confusing, contradictory, and challenging or impossible to follow. That in turn, would interfere with safe and effective use of pesticides.

Therefore, rather than promoting FIFRA's objectives, including the important goal of national labeling uniformity, damages claims for failure to warn or inadequate labeling would make them exceedingly difficult to accomplish, if not unattainable. As a result, FIFRA's "policy [of uniformity] by itself favors pre-emption of state tort suits, for the rules of law that judges and juries create or apply in such suits may themselves similarly create uncertainty and even conflict, say, when different juries in different States reach different deci-

sions on similar facts." *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 871 (2000). Rather than "complementing" EPA's regulation of pesticides and their labeling, such suits "would take from those who would enforce a federal law the very ability to achieve the law's congressionally mandated objectives that the Constitution, through the operation of ordinary pre-emption principles, seeks to protect." *Id.* at 872.

III. CONGRESS DID NOT INTEND TO EXCLUDE FROM FIFRA PREEMPTION LABELING-RELATED DAMAGES CLAIMS THAT INVOLVE AGRICULTURAL CROP INJURY

Petitioners contend that even if § 136v(b) reaches damages claims, it does not apply to labeling-related claims which directly or indirectly allege that an agricultural pesticide's labeling was inadequate to prevent crop injury. *See* Pet. Br. at 29. Nothing in the plain, broad, preemptive language of § 136v(b), however, excludes state-imposed labeling requirements that involve agricultural crop injury or product efficacy. "When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and what that provision provides a 'reliable indicium of congressional intent with respect to state authority,' *Malone v. White Motor Corp.*, 435 U.S., at 505, 'there is no need to infer congressional intent to pre-empt state laws from the *substantive provisions*' of the legislation." *Cipollone*, 505 U.S. at 517 (emphasis added). Nevertheless, Petitioners erroneously infer from one of FIFRA's substantive provisions, the efficacy data waiver authorization contained in § 136a(c)(5) of the statute's pesticide registration section, that Congress intended to create a gaping exception to preemption under § 136v(b) for labeling-related damages claims that involve efficacy-related agricultural crop injury. To the contrary, there is no basis for assuming that by enacting the 1978 efficacy data waiver

authorization as one of many federal registration refinements requested by EPA, Congress intended to upset the fundamental allocation of regulatory authority between EPA and the states, and specifically EPA's exclusive authority to regulate nationally uniform pesticide labeling, which was so carefully considered only six years earlier when Congress rewrote FIFRA and enacted § 136v(b). If Petitioners' unfounded view of the (nonexistent) relationship between the efficacy data waiver authorization and § 136v(b) were correct, it would follow *a fortiori* that for more than 25 years the states have been free to enact statutes or issue agency rules that regulate pesticide labeling to prevent efficacy-related crop injury. Not surprisingly, despite the supposed "regulatory gap" created by EPA's efficacy data waiver policy (Br. for Natural Resources Defense Council at 23), neither Petitioners nor their *amici* have pointed to any such state positive enactments.

There is no indication in the legislative history of the Federal Pesticide Act of 1978 that Congress intended the efficacy data waiver authorization of § 136c(5)(a) to amend or otherwise affect § 136v(b) in any manner. Instead, the efficacy data waiver authorization was one of a number of pesticide registration-related amendments which EPA requested during 1977-78 because under the 1972 Act, the federal "registration and reregistration process has ground to a virtual halt." S. Rep. No. 95-334, at 3 (July 6, 1977); *see* H.R. Rep. No. 95-343, at 6 (May 16, 1977) (Stmnt. of Douglas M. Costle, Admin., EPA) (discussing "specifics about correcting the difficulties which currently beset the pesticides regulatory program"). "The [1978] amendments [were] designed to improve the operation of the Federal pesticide registration program and facilitate the implementation of the major changes in that program made by the 1972 amendments to the Act." S. Rep. No. 95-334, at 1; *see also* Stmnt. of Sen. Leahy on Consideration of the Conf. Rpt.

on S. 1678, September 18, 1978, at 1-2, Sen. Comm. on Agric., Nutrition & Forestry, 95th Cong. (Comm. Print 1979) ("This bill will break the logjam in the reregistration process"). The 1978 amendments to FIFRA's registration and reregistration provisions included changes to the data consideration, data compensation, and trade secrets provisions with regard to the granting of "generic" (*i.e.*, me-too) pesticide registrations (*see Ruckelshaus*, 467 U.S. at 993-94); expedited registration procedures for "formulator" products containing registered active ingredients purchased from another company; provisions for the granting of "conditional" registrations prior to submission of all data required for registration or reregistration; provisions relating to registration of pesticides for "minor" agricultural uses; extension of the period for reregistering previously registered pesticides; and the efficacy data waiver authorization. *See* S. Rep. No. 95-1188 (Sept. 12, 1978). Upon signing the Federal Pesticide Act of 1978, President Carter stated that "[w]ith these amendments, the important task of registering pesticides may move forward in a more streamlined and efficient manner." 14 Weekly Comp. Pres. Doc. 1696 (Oct. 2, 1978).

As to the specific need for the efficacy data waiver authorization, EPA Administrator Costle testified in April 1977 "we feel that far too much Agency time is currently being spent in reviewing efficacy data *while shortages abound in the reregistration data validation areas*." H.R. Rep. No. 95-343, at 9 (May 16, 1977) (emphasis added); *see also* 44 Fed. Reg. 27,932, 27,938 (May 11, 1979) ("The decision to pursue efficacy waiver as an Agency policy stemmed from a need to reduce the amount of resources devoted to reviewing product performance *so that additional effort could be devoted to the evaluation of health and safety data, and from a desire to reduce regulatory burdens in pesticide registration.*") (emphasis added). Therefore, "the purpose of Congress" (*Cipollone*, 505 U.S. at 516) in enacting the efficacy data

waiver authorization had nothing whatsoever to do with preemption of state law. Instead, "Congress intended to give EPA broad discretion to determine how best to expend its limited resources reviewing pesticides." 48 Fed. Reg. 34,000, 34,001 (July 26, 1983); *see also* S. Rep. No. 95-334, at 3 ("The expenditure of resources by the [EPA] in reviewing efficacy data is not the best use of resources since a pesticide manufacturer is not likely to expend the substantial investment in time and money needed to obtain registration of a pesticide on a non-efficacious product."). Petitioners' theory that § 136v(b) only applies when manufacturers submit to EPA for review, data on a particular subject (*e.g.*, efficacy) *defeats the very purpose of the waiver*, which is to afford EPA flexibility to efficiently allocate its limited scientific resources by requiring submission of efficacy data only when and if crop damage problems develop after a product is registered and in use.

Moreover, the labeling-related crop injury claims which Petitioners incorrectly assert the efficacy data waiver authorization excludes from preemption, would conflict with how Congress intended review of product efficacy to work. The provision's legislative history explains that if "the Administrator found that *some other procedure for assuring the efficacy of pesticide products appeared to be sufficient* [he] could register or reregister products without requiring submission or citation of *some or all* of the efficacy data that otherwise would be required under FIFRA." H.R. Rep. No. 95-663, at 27 (1977) (emphasis added).

> This authority would be used most commonly with respect to agricultural pesticides, due to the *high level of knowledge concerning pesticidal efficacy which prevails in the agricultural community*, the existence of means for communicating efficacy information to users, the *organizational expertise of the Department of Agricul-*

> *ture, the Extension Services, and the universities* in this area, and the *stake the industry has in marketing products that are efficacious.*

Id. (emphasis added). Along the same lines, when EPA adopted its efficacy data waiver policy pursuant to § 3a(c)(5), the Agency indicated that "the efficacy of agricultural pesticides can be effectively regulated by the marketplace (*in conjunction with extension services and university research personnel*). 44 Fed. Reg. at 27,938 (emphasis added). Thus, both Congress and EPA indicated that waiving submission of efficacy data was possible because of the considerable, efficacy-related *knowledge* and *expertise* present within the agricultural community. Regulation of labeling by lay jurors, who lack the high level of knowledge and expertise contemplated by Congress, would be incompatible with, and seriously undermine, the type of expert "marketplace regulation"—not courtroom regulation—that Congress and EPA envisioned.

Unless preempted, labeling-related claims involving agricultural crop injury would wreak the same havoc with national labeling uniformity as labeling-related damages claims involving any other subject. Petitioners' premise that there are no pertinent labeling "requirements" because EPA has abandoned regulation of labeling in connection with product efficacy and crop injury prevention is belied by the actual language of the Agency's efficacy data waiver. *See* 40 C.F.R. § 158.640(b)(1) ("The Agency has waived all requirements to submit efficacy data. . . . *However*, each registrant *must ensure through testing* that his products are efficacious when used *in accordance with label directions* and commonly accepted pest control practices. The Agency *reserves the right to require*, on a case-by-case basis, *submission of efficacy data* for any pesticide product") (emphasis added). Thus, for most products (but not including the Strongarm product at issue here) EPA merely has waived the automatic

submission of efficacy data at the time a product is first registered. When EPA adopted this policy, it explained that "[t]he Administrator reserves the right to request submission of efficacy data in support of label claims *for any registered product*. A request may be made *for any product for which a pattern of inadequate performance* has been reported." 44 Fed. Reg. at 27,939 (emphasis added). Accordingly, when and if efficacy-related problems develop after a pesticide product has been registered and used by farmers, EPA has the authority, both under FIFRA and its own efficacy data waiver regulation, to require submission of efficacy data and regulate the product's nationally uniform labeling to prevent crop injury. Nothing about the efficacy data waiver authorization or the selective manner in which EPA has implemented it changes the fact that any requirements for labeling imposed through state damages claims for crop injury necessarily would be "in addition to or different from" the requirements for labeling imposed by EPA under FIFRA, and therefore, expressly preempted by § 136v(b).

The Texas Supreme Court in *American Cyanamid v. Geye*, which involved the same FIFRA preemption issue, got it wrong. The court acknowledged that "[t]his is an express preemption case," but instead of focusing on the language of § 136v(b), erroneously indicated that "*EPA regulations* define 'the domain expressly pre-empted.'" 79 S.W.3d at 24 (quoting *Cipollone*, 505 U.S. at 517) (emphasis added). The court then mistakenly assumed that EPA's efficacy data policy means that the Agency never regulates labeling to prevent crop injury. *Id.* at 25. The federal courts of appeals have reached the opposite and correct conclusion. *See, e.g., Kuiper*; *Welchert*; *Taylor*; *Worm*. As the Fifth Circuit explained in its opinion below,

> We find *Geye* unhelpful because *it did not address the principal issue: whether the scope of FIFRA's express preemption clause includes product effectiveness claims*

> *which relate to product labeling. Geye* holds only that the specific Texas state-law claims for crop damage did not present a problem of conflict preemption. . . . The scope of FIFRA's express preemption clause is defined by the simple text of § 136v. That the EPA has not elected to impose labeling regulations concerning product effectiveness *does not alter the plain meaning of § 136v(b) nor avoid preemption of a claim that has the effect of imposing labeling requirements.*

Pet. App. 14a-15a (emphasis added).

CONCLUSION

The Fifth Circuit's opinion should be affirmed.

Respectfully submitted,

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DENNIS BATES, *et al.*,

Petitioners,

v.

DOW AGROSCIENCES LLC,

Respondent.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURTS OF APPEALS
FOR THE FIFTH CIRCUIT

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INTEREST OF *AMICUS CURIAE*

The Defense Research Institute ("DRI") is an organization with members throughout the United States numbering in excess of 21,000. It seeks to advance the cause of the civil justice system in America by ensuring that the concerns of the defense bar and potential defendants are properly and adequately represented. These objectives are accomplished through the publishing of scholarly material, educating the bar by conducting seminars on specialized areas of law, and through testimony before Congress and state legislatures on select legislation impacting the civil justice system. DRI provides a forum for the networking of state and local defense organizations who share a concern for the proper and efficient operation of the civil justice system.[1]

SUMMARY OF THE ARGUMENT

Petitioners are peanut farmers in Texas who claimed that their peanut crops were damaged by an herbicide named Strongarm, which is manufactured and sold by Respondent, Dow Agrosciences LLC ("Dow"). Dow filed a declaratory judgment action in the United States District Court for the Northern District of Texas (Lubbock Division) against the Petitioners asking the court to declare, *inter alia*, that all of the farmers' causes of action are expressly and impliedly pre-empted under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136, *et seq.* The Court granted the summary judgment on pre-emption and other grounds.

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1. Pursuant to Rule 37(6) of the Supreme Court of the United States, DRI states that counsel for Petitioner and Respondent had no part in authoring any portion of this brief. No one other than DRI made a monetary contribution to the preparation or submission of this brief. Pursuant to Rule 37(3)(a) of the Supreme Court of the United States, DRI states that all parties to this case have consented to the filing of amicus curiae briefs.

The farmers (Petitioners) then appealed to the Fifth Circuit, which found that all of the claims were pre-empted under the express pre-emption doctrine because, after analyzing each cause of action, the Court determined that all of the claims boiled down to the contention that Strongarm damaged peanut crops in soil with a pH level over 7.0, an effect not disclosed to the Petitioners on the FIFRA mandated label. The Court found that success on these claims would induce Dow to change its EPA-approved label, and thus, were pre-empted under FIFRA.

The Fifth Circuit correctly affirmed the judgment of the trial court that the claims made by the Petitioners are pre-empted under the express pre-emption doctrine. The lower court properly applied the rules of law set forth in this Court's opinion in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) in finding that the Petitioners' claims are expressly pre-empted.

In addition to express pre-emption, the Court can and should consider implied pre-emption under FIFRA. Because of the EPA's pervasive registration and labeling requirements governing pesticides like Strongarm, Petitioners' claims are barred under principles of implied conflicts pre-emption. For this additional reason, the Court should affirm the Fifth Circuit's opinion, and hold that the Petitioners' claims are barred on the basis of either express or implied pre-emption.

ARGUMENT

A. FIFRA Expressly Pre-empts Petitioners' Claims

1. The Text Of § 136v(b) Compels Pre-emption

Article VI of the Constitution provides that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2. Since this Court's decision in *McCulloch v. Maryland*, 17 U.S. (4 Weat.) 316, 427 (1819), state law that conflicts with federal law is "without effect." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981).

The plain meaning of FIFRA's express pre-emption clause mandates pre-emption of certain state law claims. Section 136v of FIFRA states:

> (a) In General
>
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.
>
> (b) Uniformity
>
> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

7 U.S.C. § 136v. The plain meaning of the express pre-emption clause in FIFRA demonstrates that Congress intended to pre-empt certain state law claims. That clause mirrors the pre-emption statute in the Public Health Cigarette

Smoking Act of 1969 (the "1969 Smoking Act") that this Court considered in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). This Court addressed whether the 1969 Smoking Act and its 1965 predecessor pre-empted the plaintiff's common-law claims against the cigarette manufacturers. *Id.* at 508. The 1965 and 1969 Smoking Acts required manufacturers to place the following warning (or a variation) on every package of cigarettes sold in the United States: "WARNING: THE SURGEON GENERAL HAS DETERMINED THAT CIGARETTE SMOKING IS DANGEROUS TO YOUR HEALTH." *Id.* The 1965 version of the federal statute contained a narrow pre-emption provision as follows: "No statement related to smoking and health shall be required in the advertising of [properly labeled] cigarettes." *Id.* at 518. The Public Health Cigarette Smoking Act of 1969, which modified the 1965 Act, contains a broader express pre-emption provision that reads as follows:

> (b) No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provision of this Act.

Id. at 515 (citing § 5(b) of the Public Health Cigarette Smoking Act of 1969). The language of the express pre-emption clauses in the 1969 Smoking Act and FIFRA are strikingly similar. The Seventh Circuit has suggested that "not even the most dedicated hair splitter could distinguish these statements." *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 371 (7th Cir. 1993).

In both pre-emption clauses, this Court reasoned that the pre-emptive scope of the 1965 and 1969 Acts is "governed entirely by the express language" in the pre-emption clause. *Id.* at 517. Specifically, this Court stated,

> When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a reliable indicum of congressional intent with respect to state authority, there is no need to infer congressional intent to pre-empt state laws from the substantive provisions of the legislation.

Cipollone, 505 U.S. at 517 (internal quotations and citations omitted).

This Court determined that the 1965 Act's pre-emption clause, which contained the phrase "statements" instead of "regulations," merely prohibited state rulemaking bodies from mandating "positive enactments by legislatures or administrative agencies that mandate particular warning levels." *Id.* at 519. In contrast, the Court determined that 1969 Smoking Act's pre-emption statute, which prohibited "requirements" to preclude state regulation either by statute or by common law. *Id.* at 521-22. Even though portions of the legislative history suggested that Congress was primarily concerned with positive enactments, this Court gave effect to the plain meaning of the statute and determined that no "good reason [exists] to believe" that Congress meant less than what it said. *Id.* at 522.

Like the 1969 Smoking Act, FIFRA prohibits "any requirements" made by a state that relate to pesticide labeling. 7 U.S.C. § 136v(b). Because of the similarity between the pre-emption provisions in the 1969 Smoking Act and FIFRA, every federal circuit court that has considered FIFRA pre-emption

since *Cipollone* has held that FIFRA expressly pre-empts failure to warn or labeling claims.[2]

2. *Medtronic* Does Not Change The Pre-emption Analysis Of *Cipollone*

Petitioners and their Amici argue that this case should be controlled by this Court's opinion in *Medtronic v. Lohr*, 518 U.S. 470, 484 (1996), in which the Court interpreted the pre-emption provision in the Medical Device Amendments ("MDA"). The pre-emption statute in the MDA stated as follows:

> § 360k. State and local requirements respecting devices
>
> (a) General Rule
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may

2. *See Lowe's Home Ctrs., Inc. v. Olin Corp.*, 313 F.3d 1307 (11th Cir. 2002), *reh'g and reh'g en banc denied*, 61 Fed. Appx 673 (11th Cir. 2003); *Netland v. Hess & Clark, Inc.* 284 F.3d 895 (8th Cir. 2002), *cert. denied*, 123 S. Ct. 415 (2002); *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199 (9th Cir. 2002); *Hawkins v. Leslie's Poolmart, Inc.*, 184 F.3d 244 (3d Cir. 1999); *Andrus v. AgrEvo USA Co.*, 178 F.3d 395 (5th Cir. 1999); *Nat'l Bank of Commerce v. Dow Chem. Co.*, 165 F.3d 602 (8th Cir. 1999); *Kuiper v. Am. Cyanamid Co.*, 131 F.3d 656 (7th Cir. 1997); *Grenier v. Vermont Log Bldgs., Inc.*, 96 F.3d 559 (1st Cir. 1996); *Welchert v. Am. Cyanamid, Inc.*, 59 F.3d 69 (8th Cir. 1995); *Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555 (9th Cir. 1995); *Lowe v. Sporicidin Int'l*, 47 F.3d 124 (4th Cir. 1995); *Bice v. Leslie's Poolmart, Inc.*, 39 F.3d 887 (8th Cir. 1994); *MacDonald v. Monsanto Co.*, 27 F.3d 1021 (5th Cir. 1994); *Worm v. Am. Cyanamid Co.*, 5 F.3d 744 (4th Cir. 1993); *King v. E.I. DuPont de Nemours & Co.*, 996 F.2d 1346 (1st Cir. 1993), *cert. denied*, 510 U.S. 985 (1993); *Shaw*, 994 F.2d 364; *Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir. 1993), *cert. denied*, 510 U.S. 913 (1993); *Arkansas-Platte & Gulf P'ship v. Van Waters & Rogers, Inc.*, 981 F.2d 1177 (10th Cir. 1993), *cert. denied*, 510 U.S. 813 (1993).

> establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.
>
> (b) Exempt requirements
>
> Upon application of a state or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—
>
> (1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
>
> (2) the requirement—
>
> (A) is required by compelling local conditions; and
>
> (B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.
>
> 21 U.S.C. § 360k.

This Court's analysis of whether pre-emption exists under this statute was similar to the analysis conducted in *Cipollone*. Although the examination of the pre-emption statute must begin with its text, the interpretation of that language does not occur in a contextual vacuum, but instead is informed by two presumptions about the nature of pre-emption. *Lohr*, 518 U.S. at 485. First, the Court presumes Congress does not cavalierly pre-empt state-law causes of action. *Id.* Second, the purpose of Congress is the ultimate touchstone in every pre-emption case and any understanding of the scope of a pre-emption statute must rest primarily on "a fair understanding of congressional purpose." *Id.* at 486. Congressional purpose is determined from the structure and purpose of the statute as a whole. *Id.*

This Court determined the Congressional purpose in enacting the express pre-emption clause of the MDA by examining the unique grant of authority that Congress delegated to the Food and Drug Administration ("FDA") in determining the scope of pre-emption under § 360k(b) the MDA. This Court found the MDA pre-emption clause differed from the 1969 Smoking Act's pre-emption clause:

> Unlike the statute construed in *Cipollone*, for instance, pre-emption under the MDA does not arise directly as a result of the enactment of the statute; rather, in most cases a state law will be pre-empted only to the extent that the FDA has promulgated a relevant federal "requirement." Because the FDA is the federal agency to which Congress has delegated its authority to implement the provision of the Act, the agency is uniquely qualified to determine whether a particular form of state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," and therefore, whether it should be pre-empted. For

> example, Congress explicitly delegated to the FDA the authority to exempt state regulations from the pre-emptive effect of the MDA—an authority that necessarily requires the FDA to assess the pre-emptive effect that the Act and its own regulations will have on state laws . . . The ambiguity in the statute—and the congressional grant of authority to the agency on the matter contained within it—provide a "sound basis," . . . for giving substantial weight to the agency's view of the statute . . .
>
> The regulations promulgated by the FDA expressly support the conclusion that § 360k "does not pre-empt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the Act."

Medtronic, 518 U.S. at 496-97 (citations omitted). FIFRA, unlike § 360k(b) of the MDA, does not grant the EPA authority to exempt a state from the express pre-emption clause of § 360k(a). Because FIFRA does not provide for such a waiver, the express pre-emption clause in FIFRA is automatic and self-executing. Therefore, the pre-emption provision in FIFRA tracks the pre-emption provision from the 1969 Smoking Act interpreted in *Cipollone* rather than the MDA provision that is the subject of *Medtronic*. Therefore, this Court should follow the analysis in the *Cipollone* opinion to find express pre-emption in this case.

3. The Scope Of FIFRA Pre-emption Covers All Label-Based Claims

DRI does not contend that FIFRA expressly pre-empts all possible claims related to agricultural pesticides. However, DRI contends that FIFRA expressly pre-empts all claims based on the FIFRA-required label. Whether a claim is label-based or

not label-based does not depend on the name of the claim, but instead depends upon a case-by-case determination of the relief sought by the claimant. If a plaintiff's claim challenges the FIFRA-required label, or if the effect of the claim would induce the manufacturer to alter the FIFRA-required label, then the claim is expressly pre-empted. If the plaintiff's claim does not challenge the FIFRA-required label or induce the manufacturer to alter the FIFRA-required label, then the claim is not expressly pre-empted. For example, a claim that a manufacturer failed to follow the EPA-approved formula for a pesticide is not label-related; and, therefore, FIFRA pre-emption does not apply. However, a claim that a manufacturer failed to warn users that a pesticide should be used only in certain soils (the allegation in this case) is clearly label-related, and FIFRA pre-emption applies.

a. All Claims That Would Induce A Manufacturer To Alter Its Label Are Pre-empted

The court of appeals below held that FIFRA expressly pre-empted all of Petitioners' claims (breach of warranty, fraud, deceptive trade practices, strict tort liability and negligence) "because success on such claims would necessarily induce Dow to alter its product label." *Dow Agrosciences LLC v. Bates*, 332 F.2d 323, 333 (5th Cir. 2003), *cert. granted*, 72 U.S.L.W. 3184 (June 28, 2004). The lower court's reasoning follows this Court's analysis in *Cipollone*. The petitioner-plaintiff in *Cipollone* argued that common-law damage actions do not impose "requirements or prohibitions" (the language in the pre-emption statute of the 1969 Smoking Act), but this Court disagreed. This Court has said, "[state] regulation can be as effectively asserted through an award of damages as through some form of preventative relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." *Cipollone*, 505 U.S. 504, 521 (1992)

(citing *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)). If Petitioners in Texas may recover on state law claims based upon a warning label approved by the EPA, the obligation to pay the award of damages may cause Dow to alter its product label, and this would defeat the Congressional purpose in the "uniformity" sought by the express pre-emption clause of 7 U.S.C. § 136v(b).

Amici for Petitioner suggest that because FIFRA specifically regulates false or misleading statements, state tort claims for misrepresentation or fraud are not "different" than FIFRA's requirements, but merely provide a different remedy. It is exactly that possibility—the risk of a "different remedy"—that might compel a manufacturer to alter their label contrary to the intent of the pre-emption clause of FIFRA. This Court has previously recognized that allowing a different remedy, as determined by individual juries across the country, will disrupt any uniform approach. "This policy [of uniformity] by itself favors pre-emption of state tort suits, for the rules of law that judges and juries create or apply in such suits may themselves similarly create uncertainty and even conflict, say when different juries in different States reach different decisions on similar facts." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 871 (2000). As Justice Breyer has commented,

> The effects of the state agency regulating and the state tort suit are identical. To distinguish between them for pre-emption purposes would grant greater power (to set state standards 'different from, or in addition to' federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes. Where Congress likely did

> not focus specifically upon the matter, I would not take it to have intended this anomalous result.

Lohr, 518 U.S. at 504 (Breyer, J., concurring in part and concurring in the judgment).

The claims asserted by Petitioners constitute label-based claims. Petitioners do not claim the Strongarm product is defective in all applications, but merely in soil with a pH level over 7.0. Petitioners essentially claim that the FIFRA mandated label should contain a warning not to apply the product to soil with a pH level over 7.0. Petitioners' success on these claims would induce Dow to change its EPA-approved label. Thus, the lower court correctly determined that Petitioners claims are label-based, and are therefore expressly pre-empted by FIFRA.

b. Label-Based Claims Related To Efficacy Are Pre-empted

Petitioners and their Amici argue that efficacy claims are not pre-empted because Congress amended FIFRA in 1978 to allow the EPA to waive the submission of efficacy data during the registration of a pesticide. *See* Federal Pesticide Act of 1978, Pub. L. No. 95-396, § 5, 92 Stat. 819. However, this data submission waiver does not alter the plain meaning of § 136v(b), which states, "[A] state shall not impose or continue in effect *any* requirements for labeling or packaging *in addition to or different from* those required under this subchapter." 7 U.S.C. § 136v(b) (emphasis added). The Fifth Circuit reasoned that allowing a state to create a labeling requirement by authorizing a state law tort claim linked to the specification of a label, even where the EPA has elected not to impose such labeling requirements, would clearly impose a requirement "in addition to or different from those" required under FIFRA. *Bates*, 332 F.2d at 331.

Petitioners' efficacy claims are subject to FIFRA's express pre-emption clause if they are related to the content of the Strongarm label. *Id.*

Although the EPA may initially waive the submission of efficacy data for pesticides at the time of registration, pesticide efficacy does not remain unregulated by the EPA. Pesticide registrants must generate efficacy data, balance that data with the proposed label instructions, and hold that data ready for EPA review as it may require. 40 C.F.R. § 158.640(b)(1). The EPA may review and require data if efficacy-related problems develop after initial registration. *See* 40 C.F.R. § 158.640(b) (EPA "reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration."). The EPA also will require submission of efficacy data if "a pattern of inaccurate, outdated, or ambiguous use directions is determined to be a major problem." 49 Fed. Reg. 37,960, 37,961 (Sept. 26, 1984). Additionally, FIFRA requires the reporting of any significant crop damage caused by the manufacturer's products, which includes reports of inefficacious products. *See* 40 C.F.R. § 159.184 (c)(5)(iv). This information may lead to revisions of a product's labeling to mitigate any further risk of crop damage. *See* 62 Fed. Reg. 49, 370, 49, 372 (1997). The EPA maintains the continuing responsibility to review crop damage reports, and the EPA may levy fines against pesticide manufacturers that fail to report such crop damage. *See* 7 U.S.C. § 136*l*. Section 136a(c)(5) did not waive regulation by EPA of efficacy issues, it merely changed the methods for that regulation.

Additionally, while Texas or any other state may not impose its own requirements for labeling, it can restrict or prohibit the sale or use of products that it determines are

inefficacious. Section 136v(a) of FIFRA provides that a "State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter." § 136v(a); *see also* TEX. AGRIC. CODE ANN. § 76.001, *et seq.* Congress granted states the ability to regulate efficacy issues. However, the express pre-emption clause in § 136v(b) precludes states from "impos[ing] or continu[ing] in effect any requirements for labeling or packaging in addition to or different from those required" by FIFRA.

Therefore, the argument of the Petitioners and their Amici that a pesticide's efficacy is not regulated by EPA is clearly wrong. The EPA can examine the required efficacy data at any time and require changes in the label based on that data. The states can ban a pesticide from sale in that state but cannot by statute, regulation, or common law action, establish requirements regarding labeling of the product.

The lower court correctly concluded that FIFRA expressly pre-empted Petitioners' label-based claims. However, as demonstrated in the next section, the lower court could have also concluded that FIFRA pre-empts Petitioners' claims by implication because those state law claims conflict with the EPA's comprehensive regulatory regime governing pesticides.

B. FIFRA Pre-empts Petitioners' Claims By Implication

1. Despite The Existence Of FIFRA's Express Pre-emption, The Court Should Consider The Issue Of Implied Pre-emption.

Separate and distinct from the contours of express pre-emption is the doctrine of implied conflicts pre-emption. Pre-emption may be implied when congressional intent to pre-empt is implicitly contained in the structure and purpose of the statute. *FMC Corp. v. Holliday*, 498 U.S. 52, 56-57 (1990). The Court has found conflict pre-emption where state law "'under the circumstances of th[e] particular case . . . stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress' — whether that 'obstacle' goes by the name of 'conflicting; contrary to; . . . repugnance; difference; irreconcilability; inconsistency; violation; curtailment; ...interference' or the like." *Geier*, 529 U.S. at 873 (internal citations omitted). As a practical matter, no functional distinction exists between conflicts that "prevent or frustrate the accomplishment of a federal objective" and conflicts that make it impossible to "comply with both state and federal law" — the Supremacy Clause trumps and "nullifies" both forms of conflicting state law. *Id.* at 873.

Dow AgroSciences raised the issue of implied pre-emption in the courts below. Dow's Complaint for Declaratory Relief and Dow's First Amended Complaint for Declaratory Relief both asserted (in identical language) that Petitioner's state law claims were impliedly pre-empted by FIFRA's extensive regulatory regime:

> [Petitioners'] claims are also impliedly pre-empted by federal law because they (1) conflict with FIFRA's regulatory scheme and (2) directly

> conflict with the express authority given to registrants — such as Dow AgroSciences — to "distribute or sell a registered product with the composition, packaging and labeling currently approved by the Agency."

(Dow AgroSciences' Complaint for Declaratory Relief, at ¶ 45, JA 21; Dow AgroSciences' First Amended Complaint for Declaratory Relief, at ¶ 45, JA 203).

The court of appeals, however, did not conduct an independent analysis of implied pre-emption issues under FIFRA properly raised by Respondent because it found that Petitioners' causes of action were expressly pre-empted. Courts should, however, conduct an analysis of implied pre-emption issues, irrespective of whether the statute in question also contains an express pre-emption provision.

In *Freightliner Corp. v. Myrick*, this Court considered both express and implied pre-emption issues under the National Traffic and Motor Vehicle Safety Act of 1966 and its implementing provisions. 514 U.S. 280, 283 (1995). The respondents in *Freightliner* argued that implied pre-emption cannot exist when the statute in question contains an express pre-emption clause. This Court found this argument to be "without merit." *Id.* at 287. This Court specifically held that the existence of an express pre-emption provision in a statute does not eliminate the need for consideration of implied pre-emption issues where appropriate. *Id.* at 288-89 (noting that *Cipollone* does not establish a rule that an express preemption clause forecloses implied preemption); *see also Geier*, 529 U.S. 861, 872-74; *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 352 (2001) (considering express and implied pre-emption under the Food, Drug and Cosmetic Act and the Medical

Device Amendments of 1976 and concluding "[t]o the extent respondent posits that anything other than our ordinary pre-emption principles apply under these circumstances, that contention must fail in light of our conclusion last Term in [*Geier*] that neither an express pre-emption provision nor a saving clause 'bar[s] the ordinary working of conflict pre-emption principles.'") (quoting *Geier*) (internal citations omitted). For these reasons, the Court should examine whether FIFRA impliedly pre-empts Petitioners' causes of action. In this case, such an examination leads to the inescapable conclusion that FIFRA's intense regulatory regime governing the labeling and registration of pesticide products impliedly pre-empts state law claims such as those raised by the Petitioners.

2. Federal Regulations May Pre-empt Conflicting State Laws Even In The Absence Of Express Congressional Intent To Pre-empt, And Are Not Subject To A Presumption Against Pre-emption.

The Court has recognized that a federal statute "implicitly overrides state law either when the scope of a statute indicates that Congress intended federal law to occupy a field exclusively, or when state law is in actual conflict with federal law." *Freightliner*, 514 U.S. at 287. The Court has found implied conflict pre-emption in cases in which it is not possible for a private party to comply simultaneously with both state and federal requirements. *See English v. Gen Elec. Co.*, 496 U.S. 73, 78-79 (1990). The Court has also found implied conflict pre-emption where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Congressional intent to displace state law can be inferred where a "scheme of federal regulation may be so pervasive as to make reasonable the

inference that Congress left no room for the States to supplement it." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). This can occur either where an act of Congress

> 'may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject,' or because 'the object sought to be obtained by federal law and the character of the obligations imposed by it may reveal the same purpose.'

Fidelity Fed. Sav. and Loan Assoc. v. de la Cuesta, 458 U.S. 141, 153 (1982) (quoting *Santa Fe Elevator*).

Express Congressional intent is not a factor under implied conflict pre-emption analysis. "A pre-emptive regulation's force does not depend on express congressional authorization to displace state law . . ." *de la Cuesta*, 458 U.S. at 154. The phrase "Laws of the United States" in the Supremacy Clause is broad enough to encompass "federal statutes themselves and federal regulations that are properly adopted in accordance with statutory authorization. . . ." *City of New York v. FCC*, 486 U.S. 57, 63 (1988). A federal agency acting within the scope of the authority Congress has granted it may pre-empt state regulations and displace state or local laws that would otherwise be consistent with federal law. *Id. See also La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 368-69 (1986). In a situation where the pre-emption analysis centers on the extent to which federal regulations can usurp state laws, the Court has advised that:

> . . . [T]he inquiry becomes whether the federal agency has properly exercised it own delegated authority rather than simply whether Congress has

> properly exercised the legislative power. Thus, we have emphasized that in a situation where state law is claimed to be pre-empted by federal regulation, a "narrow focus on Congress' intent to supersede state law [is] misdirected," for [a] pre-emptive regulation's force does not depend on express congressional authorization to displace state law." . . . The statutorily authorized regulations of an agency will pre-empt any state or local law that conflicts with such regulations or frustrates the purposes thereof. . . . It has long been recognized that many of the responsibilities conferred on federal agencies involve a broad grant of authority to reconcile conflicting policies.

City of New York v. FCC, 486 U.S. at 64 (internal citations omitted). Thus, conflict pre-emption differs from express pre-emption because the former depends on an identification of actual conflict, whereas the latter depends on an express congressional statement reflecting an intent to pre-empt. *Geier*, 529 U.S. at 884.

No presumption against pre-emption exists under implied conflict pre-emption analysis. The Court has instructed that "[t]he relative importance to the State of its own law is not material when there is a conflict with a valid federal law, for the Framers of our Constitution provided that federal law must prevail." *Free v. Bland*, 369 U.S. 663, 666 (1962); *see also Felder v. Casey*, 487 U.S. 131, 138 (1988) ("any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield."); *Irving v. Mazda Motor Corp.*, 136 F.3d 764, 769 (11th Cir.), *cert. denied*, 525 U.S. 1018 (1998) ("When considering implied [conflict] pre-emption, no presumption exists against pre-emption.").

In the present case, Congress enacted FIFRA to create a comprehensive regulatory scheme aimed at controlling the registration, use, sale, and labeling of pesticides. *See Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597, 601 (1991). FIFRA's express pre-emption clause is automatic, unconditional, and self-executing. FIFRA's over-arching purposes and its comprehensive regulatory structure, and the EPA's implementation of it, compels federal pre-emption separately and independently from § 136v(b)'s express pre-emptive command.

a. FIFRA's Registration Requirements Create A Pervasive Regulatory Scheme.

All pesticides sold or distributed in the United States must be registered by the Administrator of the EPA. 7 U.S.C. § 136a(a). "An application for new registration must be approved by the EPA before the product may be legally distributed or sold. . . ." 40 C.F.R. § 152.42. The registration process for pesticides is painstakingly meticulous. A list of the required contents for an application for registration can be found at 40 C.F.R. § 152.50. The applicant must file a statement which includes the complete formula of the pesticide. 7 U.S.C. § 136a(c)(1)(D). The EPA then undertakes a comprehensive review of all pertinent data and determines whether it is sufficient to satisfy the requirements of FIFRA. 40 C.F.R. § 158.80(a). The EPA's data requirements for registration are designed to "specify the types and minimum amounts of data and information the EPA requires in order to make regulatory judgments about the various kinds of pesticide products under the criteria set forth in FIFRA sections 3(c)(5)(C) and (D) and 3(c)(7). 40 C.F.R. § 158.20(b)(1). The data requirements for pesticide registration specified in this section of the regulations "pertain to product chemistry, residue chemistry, environmental fate, toxicology, reentry protection, aerial drift evaluation,

wildlife and aquatic organisms, plant protection, nontarget insects, product performance, and biochemical and microbial pesticides." 40 C.F.R. § 158.20(c). The "data requirements for registration are intended to generate data and information necessary to address concerns pertaining to the identity, composition, potential adverse effects and environmental fate of each pesticide." 40 C.F.R. § 158.202(a).

The EPA may register a pesticide only after the Administrator weighs the risks involved with the use of the product and determines that the product generally does not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(D); 7 U.S.C. § 136(a)(c)(7). Congress has defined the term "environment" to include "water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these." 7 U.S.C. § 136(j). Congress has also defined the term "unreasonable adverse effects on the environment," in relevant part, as follows:

> The term "unreasonable effects on the environment" means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food consistent with the standard under section 346a of Title 21.

7 U.S.C. § 136(bb).

In other words, the EPA may register a pesticide only after it determines, at a minimum that (1) it possesses all data necessary to make the determinations required by FIFRA with respect to the pesticide product, including data needed to characterize any incremental risk that would result from

approval of the application; and (2) approval of the application would not significantly increase the risk of any unreasonable adverse effect on the environment. 40 C.F.R. § 152.113.

The EPA's decision to register a pesticide comes only after the EPA has convinced itself that product in question does not pose an unreasonable risk of harm. Thus, by virtue of the fact that the Administrator has registered a pesticide, the EPA necessarily has concluded that the product poses no unreasonable risk of harm to the environment (including man) when properly applied, and that its packaging, testing, and accompanying labeling are reasonable and appropriate when the product is "used in accordance with widespread and commonly recognized practice." 7 U.S.C. § 136a(c)(5)(D).

This comprehensive regulatory regime reflects the fact that Congress has expressly authorized the EPA to obtain the information it needs to reach an informed decision about whether a particular pesticide should be registered. The EPA will not register any pesticide until it "has determined that, when used in accordance with widespread and commonly recognized practice, the product will not generally cause unreasonable adverse effects on the environment." 40 C.F.R. § 115.112(e). Additionally, as set forth below, the EPA will not register a pesticide until it has also determined that the "product is not misbranded as that term is defined in FIFRA[3] . . . and its labeling and packaging comply with the applicable requirements of the Act [and its implementing regulations]" 40 C.F.R. § 152.112(f). Taken together, the registration and labeling requirements authorized by Congress and implemented by the EPA constitute clear evidence of an overarching federal role in regulating pesticides.

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3. *See* 7 U.S.C. § 136(q).

b. FIFRA's Labeling Requirements Create A Pervasive Regulatory Scheme.

Because of the crucial role that product labeling plays in the registration process, Congress has equipped the EPA with substantial power to heavily regulate the design and the content of the label for a registered pesticide. 40 C.F.R. § 156.10. Congress has defined the term "label" as "the written, printed or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers." 7 U.S.C. § 136(p)(1). The term "labeling" is more broadly defined as "all labels and other written, printed, or graphic matter (A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide or device . . ." 7 U.S.C. § 136(p)(2). These definitions evidence a Congressional intent to regulate virtually any written or printed explanatory materials that accompany the sale or distribution of a pesticide, as well as information incorporated into the label by reference.

Generally, every pesticide label must clearly and prominently show the following information: (1) the name, brand, or trademark under which the product is sold; (2) the name and address of the producer, registrant, or person for whom produced; (3) the net contents of the pesticide; (4) the product registration number; (5) the producing establishment; (6) an ingredient statement; (7) hazard and precautionary statements for human, domestic animal, and environmental hazards; (8) the directions for proper use of the pesticide; and (9) the use classifications of the pesticide. 40 C.F.R. § 156.10(a)(1)(i)-(ix). All required labeling information "must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the

labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 40 C.F.R. § 156.10(2)(i).

EPA regulations also set forth stringent rules prohibiting the use of false or misleading labeling statements. A pesticide is misbranded if "its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims." 40 C.F.R. § 156.10(a)(5). Examples of statements or representations that constitute misbranding include false or misleading statements (1) about the composition of the product; (2) about the effectiveness of the product; (3) about the value of the product "for purposes other than as a pesticide or device;" (4) that improperly compare the product with other pesticides or devices; (5) obscuring the identification of active ingredients; and (6) implying government endorsement. 40 C.F.R. § 156.10(a)(5). EPA regulations also contain specific requirements concerning the content, placement, type size, and prominence of warnings and precautionary statements. 40 C.F.R. § 156.10(a)(vii); (2)(i)-(ii).

Perhaps the most fundamental aspect of a pesticide's labeling is the product's "Directions for Use." *See generally* 40 C.F.R. § 156.10(i). Pesticide labels must contain specific and detailed warnings, instructions, and directions for use, under the heading of "Directions for Use." 40 C.F.R. § 156.10(i)(2). EPA regulations require that the directions "must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects in the environment." 40 C.F.R. § 156.10(i)(1)(i). Furthermore, EPA regulations mandate that the directions for use require (1) the statement of use classification; (2) the

statement "it is a violation of Federal law to use this product in a manner inconsistent with its labeling;" (3) the sites of application (e.g. the crops, animals, areas, or objects to be treated); (4) the target pest(s) associated with each site; (5) the dosage rate associated with each pest; (6) the method of application; (7) the frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment; (8) worker protection statements; (9) specific directions concerning the storage and disposal of the pesticide and its container; and (10) any limitations or restrictions on use required to prevent unreasonable adverse effects. 40 C.F.R. § 156.10(i). FIFRA and its regulations require that the label "appear on or be securely attached to the immediate container of the pesticide product"; or, "[i]f the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is part of the package customarily distributed or sold." 40 C.F.R. § 156.10(a)(4)(i).

It cannot be reasonably disputed that Congress intended for federal rules and regulations to feature prominently, if not exclusively, in the registration and labeling requirements of pesticides. Having established federal supremacy in this area, this Court must not allow courts to impose civil liability under state law in a manner inconsistent with this national, uniform regulatory regime.

3. Compliance With FIFRA's Pervasive Registration And Labeling Requirements Provides A Sufficient Basis For Finding Implied Conflict Pre-emption.

Once the EPA registers the product and approves the label "[a] registrant may distribute or sell a registered product with the composition, packaging and labeling currently approved by the Agency." 40 C.F.R. § 152.130(a). It is a statutory violation, punishable, by both civil and criminal penalties, to use a registered product in a manner inconsistent with its labeling. 40 C.F.R. § 156.10(i)(2)(ii). When EPA registers a pesticide, the EPA has made a determination that the product adequately and sufficiently conveys all legally required warnings, precautions, and instructions for use. This determination should foreclose state law causes of action such as those alleged by the Petitioners in this case. As the Court explained in *Geier*, implied conflict pre-emption principles arising from regulatory action by federal agencies may provide additional bases for federal pre-emption, compel pre-emption more broadly than the terms of an express pre-emption provision, and may trump a statutory savings clause. This straightforward and independent analysis affirmatively negates Petitioners' claims and, through an ordinary conflicts pre-emption analysis, provides independent, additional, and broader reasons for finding pre-emption. Thus, for a jury to impose damages against the manufacturer or distributor of an EPA-approved and registered pesticide, the jury must find that the EPA (1) was simply wrong in deciding that the product's instructions for use were in fact adequate to protect public health and the environment; and (2) was also wrong in deciding that the product's warnings and precautions were in fact adequate to protect public health and the environment. This simply should not be the case. "[A] jury determination, via a state common

[law] tort judgment, that a pesticide's labeling is inadequate results in a direct conflict with the EPA's determination that the labeling is adequate to protect against health risks." *Olin*, 313 F.3d at 1311. In other words, a jury should not be permitted to conduct an *ex post facto* review of a product's composition, risks, and benefits where the EPA has already engaged in an identical exercise and determined that the product is safe if used in accordance with its label.

Federal regulations have the same pre-emptive effect as federal statutes. *Id.* Under implied conflict pre-emption analysis, the conflict between regulations promulgated by a federal agency and state law "does not evaporate because the . . . regulation simply permits, but does not compel" the conduct in question. *Id.* at 155. Accordingly, "[a] state cannot impose common law damages on individuals for doing what a federal act or regulation 'authorized them to do.'" *Griffith v. General Motors Corp.*, 303 F.3d 1276, 1281 (11th Cir. 2002), *cert. denied*, 123 S. Ct. 1953 (2003) (quoting *Taylor v. General Motors Corp.*, 875 F.2d 816, 827 (11th Cir. 1989) (quoting, in turn, *Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 318-20 (1981)). Because the EPA's regulations expressly permit a registrant to distribute or sell its product as approved by the EPA, a jury verdict imposing damages for doing what federal regulations expressly permit is forbidden by the Supremacy Clause. "[T]he Supremacy Clause secures federal rights by according them priority whenever they come in conflict with state law." *Rondout Elec., Inc. v. NYS Dep't of Labor*, 335 F.3d 162, 166 (2d Cir. 2003) (internal citations omitted).

Petitioners cannot challenge these determinations and decisions made by the EPA after appropriate investigation and review. "To hold otherwise would be to allow state courts to sit, in effect, as super-EPA review boards that could

question the adequacy of the EPA's determination of whether a pesticide registrant successfully complied with the specific labeling requirements of its own regulations." *Welchert*, 59 F.3d at 73. "'[I]t is for the EPA administrator, not a jury, to determine whether labeling and packaging information is incomplete or inaccurate, and if so, what label changes, if any, should be made . . . We think FIFRA leaves states with no authority to police manufacturers' compliance with federal procedures.'" *Pure-Gro*, 54 F.3d at 561 (quoting *Papas*, 985 F.2d at 519).

In fact, subjecting registrants to multiple and potentially inconsistent state tort liability standards could well undermine effective enforcement of FIFRA:

> In particular, we are troubled that an applicant's disclosures under FIFRA, although not challenged by the EPA (the very agency empowered by Congress to enforce FIFRA), may be judged illegal under state law. Such an approach would force FIFRA applicants to ensure that their disclosures to the EPA would satisfy not only the standards imposed by that agency under federal law, but also the potentially heterogeneous standards propounded by each of the 50 states. Such a holding would in turn motivate potential applicants under FIFRA to "submit a deluge of information that the [EPA] neither wants not needs, resulting in additional burdens on the [EPA's] evaluation of an application." This outcome would needlessly drain the EPA of its limited resources, thereby detracting from its ability to efficiently enforce FIFRA.

Nathan Kimmel, 275 F.3d at 1207 (quoting *Buckman*, 531 U.S. at 351).

For these reasons, this Court should rule that the imposition of tort liability under state law for the sale or distribution of registered pesticides must give way to FIFRA's comprehensive regulatory scheme because imposing liability under these circumstances would deal a devastating blow to the EPA's congressional mandate to enact uniform national rules and regulations governing the safety of pesticides on public health and the environment.

CONCLUSION

Where federal law and state law conflict, federal law prevails. Uniformity in pesticide labels is a key component of the FIFRA scheme. Uniformity is difficult to be achieved if federally-approved labels may be challenged in different courts around the country. One court decision could require certain language on the label, and another court could require different language for the same label, making uniformity impossible.

In order to maintain uniformity in pesticide labels, this Court should follow it analysis in *Cipollone* and find that all of the Petitioners' claims are pre-empted under FIFRA. The Court should additionally find that all of the Petitioners' claims are pre-empted under implied pre-emption.

Respectfully submitted,

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No. 03-388

IN THE

Supreme Court of the United States

DENNIS BATES, *et al.*,
Petitioners,

v.

DOW AGROSCIENCES, LLC,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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BRIEF OF E.I. DU PONT DE NEMOURS AND COMPANY, MONSANTO COMPANY, AND SYNGENTA CROP PROTECTION, INC., AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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QUESTION PRESENTED

Whether the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136 *et seq.*, preempts petitioners' state tort claims alleging that the application of respondent's herbicide damaged petitioners' peanut crops.

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INTERESTS OF *AMICI CURIAE* [1]

Amici curiae E.I. Du Pont de Nemours and Company, Monsanto Company, and Syngenta Crop Protection, Inc., manufacture products whose labels are regulated by the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136 *et seq.* *Amici* frequently face lawsuits relating to the content of their EPA-approved labels, which are predicated on state statutory and common law theories of liability. Such lawsuits, if adjudicated under state law, would create a conflicting state-by-state patchwork of labeling and packaging requirements and thus undermine the uniform federal regulatory regime Congress created in FIFRA. *Amici* have a significant interest in the proper interpretation of FIFRA's express preemption provision to further the explicit statutory goal of uniformity.

Further, as commercial participants in a national market dependent upon regulatory consistency and uniformity, *amici* have a significant interest in the proper development and clear articulation of the general law of preemption. In particular, *amici* believe that the so-called presumption against preemption applies only in instances where "Congress has legislated in a field which the States have traditionally occupied," *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), and not "where there has been a history of significant federal presence." *United States* v. *Locke*, 529 U.S. 89, 108 (2000). Where the assumption applies that Congress does not lightly displace historic state police power, *amici* seek to ensure that it is given the proper weight as a

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[1] Petitioners and Respondent have consented to the filing of this brief. Consistent with Rule 37.6, this brief is not authored in whole or in part by counsel for any party. No person, other than *amici* or their counsel, has made a monetary contribution to the preparation or submission of this brief.

background interpretive principle and not as a dispositive presumption or clear statement rule.

STATEMENT OF THE CASE

Amici adopt the statement of the case presented in the Brief for Respondent. For the Court's convenience, *amici* set forth below the facts most salient to the analysis that follows.

Federal regulation of agricultural chemicals began with the Insecticide Act of 1910. Ch. 191, 36 Stat. 331. In 1947, Congress replaced that statute with FIFRA and required federal registration of all pesticides. FIFRA, ch. 125, §§ 3-4, 61 Stat. 166-67 (1947). FIFRA also gave the Secretary of Agriculture discretion to ask an applicant to submit a description of the tests and results supporting the information, claims and directions for use on each pesticide's label. *See* § 4a(4), 61 Stat. 167.

The Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 973, revised FIFRA in light of "a growing perception that the existing legislation was not equal to the task of safeguarding the public interest." *Ruckelshaus* v. *Monsanto Co.* 467 U.S. 986, 991 (1984). The 1972 amendment directed the EPA to register a pesticide if it determined that:

> (A) its composition is such as to warrant the proposed claims for it;
>
> (B) its labeling and other material required to be submitted comply with the requirements of this subchapter;
>
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
>
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

7 U.S.C. § 136a(c)(5). As in the original FIFRA, the 1972 amendments did not require the EPA to collect efficacy or

other data in support of product registration. Rather, it clarified the EPA's discretion to "specify the kinds of information which will be required to support the registration of a pesticide." Pub. L. No. 92-516, § 3(c), 86 Stat. 973, 979-80 (1972). The EPA then required applicants to submit data on nearly every aspect of their pesticide. *See* 40 C.F.R. Pt. 158.

Responding to EPA concerns that pre-registration evaluation encumbered too much agency resources, Congress amended FIFRA in 1978 to provide the EPA with direct authority to waive review of pesticide efficacy data during the initial registration process. 7 U.S.C. § 136a(c)(5). However, because the 1978 Amendments did not alter the underlying statutory requirement that a pesticide's "composition is such as to warrant the proposed claims for it," 7 U.S.C. § 136a(c)(5)(A), "each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration." 40 C.F.R. § 158.640(b)(1).

FIFRA expressly grants states the authority to regulate the sale or use of federally registered pesticides within their jurisdiction. "A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter." 7 U.S.C. § 136v(a). However, to ensure national uniformity in the form and content of pesticide labels, FIFRA expressly limits state authority to regulate pesticide labeling or packaging:

> **Uniformity.** Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

7 U.S.C. § 136v(b).

After a seven-year application process, which included submission of scientific data on efficacy, EPA conditionally registered Strongarm on March 8, 2000. JA 63-93. Petitioners, West Texas peanut farmers, used Strongarm and experienced poor crop yields. They sent demand letters to Dow AgroSciences alleging claims under common law and the Texas Deceptive Trade Practices Act, Tex. Bus. & Com. Code §§ 17.01 *et seq*. JA 30-40.

Dow sought a declaratory judgment in federal district court that FIFRA and the Texas Uniform Commercial Code barred the farmers' state law claims. JA 13-23. The district court granted Dow's summary judgment motion, holding that section 136v(b) expressly preempted all but one of the farmers' state law claims because those claims constituted state requirements for labeling and packaging in addition to those required under FIFRA. Pet. App. 21a-31a.

The Fifth Circuit affirmed, holding that it is "well-established" that the phrase "any requirements" in section 136v(b) encompasses both positive enactments and state common law. Pet. App. 11a. Noting that the plain text of this provision refers to the statutory requirements of FIFRA and not EPA regulatory actions, the Court rejected Petitioners' argument that their claims are not preempted because EPA does not require data on and evaluate product efficacy prior to registration. Pet. App. 12a-13a. The Fifth Circuit distinguished *American Cyanamid Co.* v. *Geye*, 79 S.W.3d 21 (Tex. 2002), as dealing only with the question of conflict preemption and not whether section 136v(b)'s express preemptive scope includes product effectiveness claims. Pet. App. 13a.

SUMMARY OF ARGUMENT

Petitioners misconstrue and give undue weight to the so-called presumption against preemption. Their argument that the presumption mandates a narrow construction of section

136v(b) and the term "requirements" rests on a misunderstanding of the Distinction between preemption and supremacy and the relationship between express and conflict preemption. The Constitution provides a straightforward structure governing the relationship between federal and state regulatory authority. Any attempt to convert the presumption against preemption from a background assumption to a clear statement rule would upend that structure, particularly where there has been a history of significant federal regulatory presence.

For nearly a century, Congress has regulated pesticide efficacy and labeling. Against this backdrop of pervasive federal regulation, the interpretive principle shifts—certainly not to disfavor, and more likely to prefer, federal displacement of state law.

Absent an artificial presumption, application of ordinary principles of statutory construction demonstrates that Congress intended to preempt state common law claims relating to the labeling of pesticides subject to FIFRA's requirements. The Court has twice held that use of the term "requirements" in express preemption provisions includes state common law tort actions. There is no reason to believe that the term has a different meaning in section 136v(b) of FIFRA.

It is irrelevant to the interpretation of section 136v(b) whether the EPA actually evaluates product efficacy before registration. Instead, the analysis turns on whether product efficacy is a requirement under FIFRA. The 1978 FIFRA amendments did not rescind the efficacy requirement, but simply authorized the EPA not to require data submission or to evaluate product efficacy prior to registration. Therefore, product efficacy is still a requirement under FIFRA and, accordingly, falls within FIFRA's preemptive scope.

ARGUMENT

I. PETITIONERS MISCONSTRUE AND THUS ASCRIBE UNDUE WEIGHT TO THE PRESUMPTION AGAINST PREEMPTION.

Petitioners' argument—that the so-called presumption against preemption dictates that the term "requirements" and the preemptive scope of section 136v(b) be narrowly construed to exclude state common law tort claims, Pet. Br. 21—rests on a misconception of the distinction between preemption and supremacy and the relationship between express and conflict preemption.

Petitioners' argument would convert a background assumption in statutory construction into a clear statement rule, without any constitutional or logical basis. To the contrary, "[t]here is not—and from the very nature of the problem there cannot be—any rigid formula or rule which can be used as a universal pattern to determine the meaning and purpose of every act of Congress." *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941). Although the Court has often repeated the assumption that Congress does not intend lightly to displace the "historic police powers of the States," the weight of this assumption turns on whether "Congress has legislated in a field which the States have traditionally occupied." *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 485 (1996) (quoting *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Thus, this assumption does not hold "where there has been a history of significant federal presence." *United States* v. *Locke*, 529 U.S. 89, 108 (2000).

Over the course of the last century, the Federal government has pervasively regulated all facets of agricultural production. That regulatory framework includes FIFRA, a "comprehensive regulatory statute." *Wisconsin Pub. Intervenor* v. *Mortier*, 501 U.S. 597, 601 (1991) (quoting *Ruckleshaus*, 467 U.S. at 991). Against this "history of significant federal

presence," *Locke*, 529 U.S. at 108, particularly with regard to pesticide labeling, *Mortier*, 501 U.S. at 613, Petitioners' insistence that the presumption against preemption favors a narrow reading of the preemptive scope of FIFRA rings hollow.

A. Ascribing Dispositive Weight to a Presumption Against Preemption Would Upend Established Principles of Constitutional Supremacy.

Petitioners' insistence that a presumption against preemption dictates a narrow interpretation of section 136v(b) rests on a fundamental misconception of the distinction between preemption and supremacy.

The Constitution provides a straightforward structure governing the scope and effect of federal and state legislative authority: Article I, section 8 enumerates the powers of Congress; Article I, section 9 limits the powers of Congress; Article I, section 10 limits the powers of the states; and the Tenth Amendment reserves to the states the powers not delegated to Congress and prohibited to the states. Importantly, clause 2 of Article VI, the Supremacy Clause, provides that congressional enactments consistent with the Constitution "shall be the supreme Law of the Land."

Although the Supremacy Clause prescribes that congressional enactments trump conflicting state law and thus gives Congress "an extraordinary power in a federalist system," *Gregory* v. *Ashcroft*, 501 U.S. 452, 460 (1991), the Clause itself does not authorize Congress to preempt state laws. The Supremacy Clause simply specifies a constitutional choice of law rule, one that prefers valid federal law over conflicting state law. If the clause were meant to be an affirmative grant of congressional power, it would reside in the metropolis of congressional power, Article I, section 8, rather than in the Article VI suburbs.

The history of the Constitution confirms the point. In the decade prior to the Constitutional Convention, internecine disputes in trade and commerce among the states underscored the need for an effective national government with the power to regulate interstate commerce. In 1786, delegates met at Annapolis, Maryland, to discu[illegible] a uniform federal system of commercial regulation. The Annapolis Convention convinced the participants, including James Madison and Alexander Hamilton, that "the power of regulating trade is of such comprehensive extent, and will enter so far into the general system of the federal government, that to give it efficacy, and to obviate questions and doubts concerning its precise nature and limits, may require a correspondent adjustment of other parts of the federal system." 1 ELLIOT'S DEBATES ON THE FEDERAL CONSTITUTION 118 (2d ed. 1907). Recognizing the need to balance state sovereignty with the necessary powers of an effective national government, the Annapolis participants recommended to Congress a general convention to remedy "the important defects in the system of the federal government." *Id.*

Against that backdrop, the Framers in 1787 considered two different approaches to federal and state legislative authority. The Virginia Plan included among its proposed congressional powers the broad authority "to negative all laws passed by the several States, contravening in the opinion of the National Legislature the articles of the Union." 1 THE RECORDS OF THE FEDERAL CONVENTION OF 1787, at 21 (M. Farrand rev. ed. 1966) (hereinafter "FARRAND"). The alternative New Jersey (or Small State) Plan, on the other hand, did not include such authority among the powers of Congress, but rather separately proposed language similar to the current Supremacy Clause.

During the debates, Madison warned against the "propensity of the States to pursue their particular interests in opposition to the general interest" and advocated "the

negative on the laws of the States as essential to the efficacy & security of the Genl. Govt." 2 FARRAND at 27. Governor Robert Morris of Pennsylvania opposed congressional power to negative state laws, explaining that "[a] law that ought to be negatived will be set aside in the Judiciary departmt. and if that security should fail; may be repealed by a Nationl. Law." *Id.* at 28. The Virginia Plan was defeated by a vote of 3 to 7.

The Convention then adopted a revised version of the New Jersey proposal almost identical to the current Supremacy Clause. *Id.* at 28-29. Consistent with the New Jersey Plan's structure and Morris's explanation, the adopted text does not mention any affirmative authority of Congress, but simply sets forth the hierarchy between federal and state laws.

Any power to preempt state law, therefore, is conferred not by the Supremacy Clause, but by the affirmative grant of congressional powers under Article I, section 8. For example, should Congress legislate pursuant to its powers under the Commerce Clause and wish to include a provision expressly preempting certain state laws, the authority for the preemption provision comes from the Commerce Clause, with help from the Necessary and Proper Clause. The Supremacy Clause then makes clear that the preemption provision trumps state laws that conflict with it.

Accordingly, if there are questions of constitutional policy in preemption—"the Danger . . . that the national, would swallow up the State Legislatures," 1 FARRAND at 160, and the like—the framers answered them with the specific enumerations and limitations of federal legislative power in Article I and the Supremacy Clause in Article VI. To find in this structure a dispositive presumption against preemption, as Petitioners urge the Court to do, is to rewrite the balance envisioned by the Framers—a balance that, it bears reminding, Madison and others thought should have been weighted even more in favor of Congress.

Preemption is not a substantive power of Congress, but rather a method of regulation to further some other substantive congressional authority. In this regard, true conflict preemption is actually not preemption at all, but the paradigmatic operation of the Supremacy Clause to resolve an actual conflict between state and federal law, where it is physically impossible to comply with both federal and state requirements. *See* Louise Weinberg, *The Federal-State Conflict of Laws: "Actual" Conflicts*, 70 TEX. L. REV. 1743, 1751 (1992).

Express preemption is simply a type of true conflict preemption, or core supremacy. In addition to any substantive regulatory requirements, Congress may choose further to include a provision preempting all state laws within a defined scope. The Supremacy Clause then makes clear that the preemption provision, like any other provision of federal law, takes precedence over conflicting state laws. All state laws within the scope of the express preemption provision are by definition in conflict with it, and the latter is supreme.

Section 136v(b) provides that States "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." Congress cannot commandeer State legislative processes, *see New York* v. *United States*, 505 U.S. 144, 161 (1992), and thus this provision does not literally prohibit states from adopting requirements for labeling and packaging. Rather, if a State adopts labeling and packaging requirements that are in addition to or different from those required by FIFRA, such requirements would conflict with section 136v(b) and the Supremacy Clause resolves the conflict in favor of FIFRA.

In this and other express preemption cases, therefore, the work of the Supremacy Clause is straightforward. It gives effect to the express preemption clause and tells state and federal judges to prefer the clause to all contrary state laws.

The judicial task is likewise limited: to interpret the express preemption clause and determine whether the state law at issue falls within the preemptive scope. This task does not call for special Supremacy Clause or preemption jurisprudence. It is garden-variety statutory construction.

Statutory construction is, by its nature, contextual. It is therefore natural for the Court to assume that Congress does not lightly displace the "historic police powers of the States," where "Congress has legislated in a field which the States have traditionally occupied." *Medtronic*, 518 U.S. at 485 (quoting *Rice*, 331 U.S. at 230). Thus, the Court in *Mortier* held that Congress's "[m]ere silence" with respect to local governments (as opposed to States) was "inadequate to convey an express preemptive intent." *Mortier*, 501 U.S. at 607.

But Petitioners' reliance on *Mortier* in this case is wholly misplaced. Here, there is no silence: Congress articulated its "express preemptive intent" in section 136v(b). The question, rather, is the scope of such intent and the specific meaning of the word "requirements." By insisting that a dispositive presumption against pre-emption works to change the natural and established meaning of "requirements," and to narrow artificially the scope of the express pre-emption provision, Petitioners would urge on this Court a clear statement rule of statutory construction.

There is no constitutional or logical support for such a rule. All other narrow construction or clear statement rules are predicated on a constitutional concern independent of the Supremacy Clause. For example, the presumption against congressional abrogation of state sovereign immunity and the attendant requirement of an "unmistakably clear" legislative statement abrogating such immunity derives from the Eleventh Amendment. *Dellmuth* v. *Muth*, 491 U.S. 223, 230 (1989); *Atascadero State Hospital* v. *Scanlon*, 473 U.S. 234, 242 (1985). Similarly, the clear statement rule of *Gregory* v.

Ashcroft, 501 U.S. 452 (1991), sprouts from the respect for state sovereign prerogative protected by the Tenth Amendment. Setting judicial qualifications "is a decision of the most fundamental sort for a sovereign entity," even though the Supremacy Clause permits Congress to "impose its will on the States." *Gregory*, 501 U.S. at 460.

Indeed, the Supremacy Clause evinces, if anything, a presumption favoring pre-emption. Without an independent constitutional basis, such as the Tenth or Eleventh Amendments, there is nothing to counterbalance the Constitution's express preference for federal supremacy. Absent a countervailing constitutional concern, finding a clear statement rule against preemption in the Supremacy Clause is akin to conjuring from the Eleventh Amendment a presumption favoring federal jurisdiction over suits against States.

As a practical matter, ascribing such dispositive weight to the presumption against preemption as Petitioners suggest would render impractical any use of express preemption and subvert the structural relationship between preemption and supremacy and between conflict and express preemption. "The statute that says anything about pre-emption must say everything; and it must do so with great exactitude, as any ambiguity concerning its scope will be read in favor of preserving state power. If this is to be the law, surely only the most sporting of Congresses will dare say anything about preemption." *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 548 (1992) (Scalia, J., concurring in part, dissenting in part).

B. Any Background Assumption Against Preemption is Contradicted by the History of Significant Federal Presence in Regulating Agricultural Production and Pesticide Marketing.

Because preemption analysis is, at bottom, an exercise in statutory construction, "[t]here is not—and from the very nature of the problem there cannot be—any rigid formula or

rule which can be used as a universal pattern to determine the meaning and purpose of every act of Congress." *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941). Rather, courts interpreting a preemption provision, like any other statutory provision, must look to the background against which Congress legislates. *See Kimel* v. *Fla. Bd. of Regents*, 528 U.S. 62, 94 (2000) (Stevens, J., dissenting) ("Whenever Congress passes a statute, it does so against the background of state law already in place; the propriety of taking national action is thus measured by the metric of the existing state norms that Congress seeks to supplement or supplant.").

Although this Court does not lightly assume that Congress intended to displace the "historic police powers of the States," the weight of this assumption naturally turns on whether "Congress has legislated in a field which the States have traditionally occupied." *Medtronic*, 518 U.S. at 485 (quoting *Rice*, 331 U.S. at 230). Stated conversely, "an 'assumption' of non-preemption is not triggered when the State regulates in an area where there has been a history of significant federal presence." *Locke*, 529 U.S. at 108 (citations omitted).

Agricultural production and pesticide labeling are areas where there has been a history of significant federal presence. As President Washington stated in his 1796 annual address to Congress, "It will not be doubted that with reference either to individual or national welfare agriculture is of primary importance . . . . Institutions for promoting it grow up, supported by the public purse; and to what object can it be dedicated with greater propriety?" BRUCE L. GARDNER, AMERICAN AGRICULTURE IN THE TWENTIETH CENTURY 176 (2002).

Recognizing the importance of agriculture to the national economy, early Congresses focused on establishing institutions to promote agricultural production. In 1862, Congress created the Department of Agriculture, 12 Stat. 387 (1862), and passed the Morrill Act, 12 Stat. 503 (1862), which

established the system of land-grant universities that still persists to this day. And in 1887, Congress passed the Hatch Act, 24 Stat. 441 (1887), which provides federal support for state agricultural experiment stations.

When the prosperity of the American farm evaporated after World War I, *see* GARDNER, *supra*, at 1, Congress responded with a host of legislative elixirs in an attempt to remedy the problem, including: price controls, Agricultural Marketing Act of 1929, 46 Stat. 11, increased tariffs, Smoot-Hawley Tariff Act, 46 Stat. 686 (1930), and supply-control measures, Agricultural Adjustment Act of 1933, 48 Stat. 31. *See also* Howard B. Pickard, *Price and Income Adjustment Programs in* 1 AGRICULTURAL LAW 3 (John H. Davidson, ed. 1981) ("Modern farm legislation had its origins from the depression years of the early 1930s."). It was also during these years that Congress began to assert the full breadth of its Article I, section 8 powers, oft-times in the name of the farm. For example, the Agricultural Adjustment Act of 1938, upheld in *Wickard* v. *Filburn*, 317 U.S. 111 (1942), stands as "perhaps the most far reaching example of Commerce Clause authority over intrastate activity." *United States* v. *Lopez*, 514 U.S. 549, 560 (1995).

In addition to the broad price-stabilizing programs of the New Deal, Congress also enacted legislation affecting almost every aspect of the farm. *See, e.g.*, Agricultural Marketing Act of 1946, Pub. L. No. 79-733, 60 Stat. 1082, codified, as amended, at 7 U.S.C. § 1621 *et seq*. (providing for the inspection, grading, packaging and labeling of agricultural products). Pesticide regulation is no exception.

For nearly a century, Congress has regulated pesticide efficacy and labeling, beginning with the Insecticide Act of 1910. Ch. 191, 36 Stat. 331. In 1947, Congress replaced that regime with FIFRA. Both statutes were aimed at "protecting consumers from the purchase of ineffective products. However, the coverage of [FIFRA] was substantially

broadened, a purpose to protect the public from the hazards associated with the use of economic poisons was implemented, and, for the first time, all economic poisons were required to be registered with the Secretary of Agriculture." *Stearns Elec. Paste Co.* v. *EPA*, 461 F.2d 293, 302 (7th Cir. 1972).

In 1954, Congress further asserted primacy over agricultural production and pesticide regulation when it amended the Federal Food, Drug, and Cosmetic Act to authorize the Secretary of Health, Education and Welfare to establish tolerances with respect to pesticide use on raw agricultural products. Pub. L. No. 83-518, 68 Stat. 511 (1954). The law specifically allowed FIFRA pesticide registrants to petition the Secretary to establish a tolerance level for their pesticides, or exempt them from the tolerance requirement. The Act required petitions to contain data showing, among other things, "full reports of investigations made with respect to the safety of the pesticide chemical." *Id*. at § 408(d).

Congress amended FIFRA in 1972 to provide increased authority to EPA and added the preemption provisions codified at 7 U.S.C. § 136v. *See* Federal Environmental Pesticide Control Act, Pub. L. No. 92-516, § 24, 86 Stat. 973, 997 (1972). These amendments further strengthened FIFRA as "a comprehensive regulatory statute,'" *Mortier*, 501 U.S. at 601 (quoting *Monsanto*, 467 U.S. at 991).

Against this backdrop, it is not reasonable to assume that Congress intended to tread lightly in preempting state law. Such an assumption may well hold where "Congress has legislated in a field which the States have traditionally occupied." *Medtronic*, 518 U.S. at 485 (quoting *Rice*, 331 U.S. at 230). In such cases, state regulation is primary, and Congress is assumed to act only interstitially. But where, as in agricultural production, Congress has legislated pervasively, the background interpretive principle shifts—certainly not to disfavor, and more likely to prefer, federal displacement of state law.

Put another way, it would seem odd in the very least to assume that, after more than sixty years of regulating pesticide labeling, Congress intended generally to protect state regulatory authority in 1972 when it further "'transformed FIFRA from a labeling law into a comprehensive regulatory statute.'" *Mortier*, 501 U.S. at 601 (quoting *Monsanto*, 467 U.S. at 991).

The proper application of the presumption against preemption is where Congress has only acted interstitially to supplement State regulation. The long and significant federal history in regulating agricultural production and pesticide marketing counsels against applying the presumption here. Instead, the Court should apply everyday principles of statutory construction in a straightforward manner, without utilizing an artificial thumb-on-the-scale presumption.

II. FIFRA EXPRESSLY PREEMPTS COMMON LAW DAMAGE CLAIMS RELATING TO LABELING OR PACKAGING.

The plain text of FIFRA demonstrates that Congress intended to displace state common law actions relating to labeling or packaging of products subject to FIFRA's statutory requirements. This Court has twice held that the term "requirements" in express preemption provisions includes common law tort actions. *See Cipollone*, 505 U.S. at 521 (plurality); *id.* at 548-49 (Scalia, J., concurring in judgment in part and dissenting in part); *Medtronic*, 518 U.S. at 504 (Breyer, J., concurring in part and concurring in judgment); *id.* at 509 (O'Connor, J., concurring in part and dissenting in part). There is no reason to think that "requirements" has a different meaning in section 136v(b). It is of no moment that section 136v(b) relates back to section 136v(a)'s authorization of states to "regulate" and its references to such state "regulation." "[State] regulation can be as effectively exerted through an award of damages as

through some form of preventive relief." *Cipollone*, 505 U.S. at 521 (quoting *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 247 (1959)).

It is irrelevant whether the Environmental Protection Agency has waived data requirements for, or actually evaluates, product efficacy prior to registering a product and approving its labeling and packaging. Section 136v(b) prohibits state law requirements for labeling and packaging other than "those required under this subchapter." Under that subchapter, section 136a(c)(7) allows EPA to conditionally register a pesticide without receiving or reviewing efficacy data, but only if, among other things, the pesticide's "composition is such as to warrant the proposed claims for it" and if "it will perform its intended function without unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5). The 1978 Amendments did not rescind or alter the requirement that the pesticide be effective, but simply authorized the EPA not to require data submission or to evaluate product efficacy prior to registration. Product efficacy is therefore still "required under this subchapter" and within section 136v(b)'s preemptive scope, regardless of the EPA's decision as to whether, when, and how to monitor compliance or enforce violations of that requirement.

A. FIFRA's Preemption of State Law "Requirements" Includes Common Law Claims for Damages.

This Court has twice held that the term "requirements" in express preemption provisions includes common law tort actions. *See Cipollone,* 505 U.S. at 521 (plurality); *id.* at 548-49 (Scalia, J., concurring in the judgment in part and dissenting in part); *Medtronic*, 518 U.S. at 504 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 509 (O'Connor, J., concurring in part and dissenting in part).

In *Cipollone*, the Court interpreted the reach of the Cigarette Labeling Act, as amended, which provided: "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87. Much like Petitioners here, Cipollone argued that the provision did not preempt common law actions. *See Cipollone*, 505 U.S. at 521 (plurality).

Six justices explicitly rejected this contention, four of them reasoning that "[t]he phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive law enactments and common law . . . ." *Id.* (Stevens, J., with whom Rehnquist, C.J., White and O'Connor, J.J., joined, writing for a plurality of the Court as to part V) (second alteration in original); *see also id.* at 548-49 (Scalia, J., with whom Thomas, J., joined, concurring in the judgment in part and dissenting in part). Writing for the four-justice plurality, Justice Stevens continued, "those words *easily* encompass obligations that take the form of common-law rules." *Id.* at 521 (plurality) (emphasis added). "The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." *Id.* (quoting *San Diego Bldg. Trades Council*, 359 U.S. at 247).

Similarly, in *Medtronic* five justices held that the word "requirements," as used in the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, "'easily'" encompassed tort actions. *Medtronic*, 518 U.S. at 504 (Breyer, J., concurring in part and concurring in the judgment) (quoting *Cipollone*, 505 U.S. at 521); *id.* at 510-11 (O'Connor, J., with whom Rehnquist, C.J., Scalia and Thomas, J.J., joined, concurring in part and dissenting in part).

There is no reason to think that the term "requirements" as used in section 136v(b) has a different meaning than in the Cigarette Labeling Act or in the Medical Device Amendments. Indeed, since *Cipollone*, the federal circuit courts have been in unanimous accord: FIFRA's preemption provision embraces state tort actions relating to the labeling or packaging of pesticides.[2] Eighteen state supreme courts agree.[3]

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[2] *Lowe's Home Cntrs., Inc.* v. *Olin Corp.*, 313 F.3d 1307 (11th Cir. 2002), *reh'g and reh'g en banc denied*, 61 Fed. Appx. 673 (11th Cir. 2003) (table); *Netland* v. *Hess & Clark, Inc.*, 284 F.3d 895 (8th Cir.), *cert. denied*, 537 U.S. 949 (2002); *Nathan Kimmel, Inc.* v. *DowElanco*, 275 F.3d 1199 (9th Cir. 2002); *Ruiz-Guzman* v. *Amvac Chem. Corp.*, 243 F.3d 549 (9th Cir. 2000); *Hawkins* v. *Leslie's Pool Mart, Inc.*, 184 F.3d 244 (3d Cir. 1999); *Andrus* v. *AgrEvo USA Co.*, 178 F.3d 395 (5th Cir. 1999); *Lescs* v. *William R. Hughes, Inc.*, 168 F.3d 482 (4th Cir. 1999), *cert. denied*, 528 U.S. 1119 (2000); *Nat'l Bank of Commerce (Arnold)* v. *Dow Chem. Co.*, 165 F.3d 602 (8th Cir. 1999); *Kuiper* v. *Am. Cyanamid Co.*, 131 F.3d 656 (7th Cir. 1997), *cert. denied*, 523 U.S. 1137 (1998); *Rodriguez* v. *Am. Cyanamid Co., Inc.*, F.3d 485, (9th Cir. 1997); *Grenier* v. *Vt. Log Bldgs., Inc.*, 96 F.3d 559 (1st Cir. 1996); *Welchert* v. *Am. Cyanamid, Inc.*, 59 F.3d 69 (8th Cir. 1995); *Taylor AG Indus.* v. *Pure-Gro*, 54 F.3d 555 (9th Cir. 1995); *Lowe* v. *Sporicidin Int'l*, 47 F.3d 124 (4th Cir. 1995); *Bice* v. *Leslie's Poolmart, Inc.*, 39 F.3d 887 (8th Cir. 1994); *MacDonald* v. *Monsanto Co.*, 27 F.3d 1021 (5th Cir. 1994); *Worm* v. *Am. Cyanamid Co.*, 5 F.3d 744 (4th Cir. 1993); *King* v. *E.I. DuPont de Nemours & Co.*, 996 F.2d 1346 (1st Cir. 1993); *Shaw* v. *Dow Brands, Inc.*, 994 F.2d 364 (7th Cir. 1993); *Papas* v. *Upjohn Co.*, 985 F.2d 516 (11th Cir.), *cert. denied sub nom. Papas* v. *Zoecon Corp.*, 510 U.S. 913 (1993); *Arkansas-Platte & Gulf P'ship* v. *Van Waters & Rogers, Inc.*, 981 F.2d 1177 (10th Cir.), *cert. denied sub nom. Arkansas-Platte & Gulf P'ship* v. *Dow Chem. Co.*, 510 U.S. 813 (1993); *see also Oken* v. *Monsanto Co.*, 371 F.3d 1312 (11th Cir. 2004).

[3] *Etcheverry* v. *Tri-Ag Service, Inc.*, 993 P.2d 366 (Cal. 2000); *Banks* v. *ICI Americas, Inc.*, 450 S.E.2d 671 (Ga. 1994); *Kawamata Farms, Inc.* v. *United Agri Prods.*, 948 P.2d 1055 (Haw. 1997); *Dow Chem. Co.* v. *Ebling*, 753 N.E.2d 633 (Ind. 2001); *Wright* v. *Am. Cyanamid Co.*, 599 N.W.2d 668 (Iowa 1999); *Ackerman* v. *Am. Cyanamid Co.*, 586 N.W.2d 208 (Iowa 1998); *Ackles* v. *Luttrell*, 561 N.W.2d 5730 (Iowa 1997);

Notwithstanding the overwhelming weight of authority, Petitioners point to the fact that "'requirements' is used 75 times in the remainder of FIFRA." Pet. Br. at 22. "The use of 'requirements' throughout FIFRA," Petitioners argue, "demonstrates that Congress understood labeling 'requirements' to refer only to labeling commands imposed by statute and regulation, . . . connoting positive commands of law." *Id.* This argument is unpersuasive. The Cigarette Labeling Act, as amended, uses "requirements" six times in different contexts outside the preemption provision. *See* 15 U.S.C. §§ 1333, 1336, 1340. Likewise, the Medical Device Amendments employ "requirement" 109 times, not counting the preemption clause. *See* 21 U.S.C. §§ 351, 352, 360, 360c, 360d, 360e, 360i, 360j. Meaning matters; numbers do not.

There is likewise little merit to Petitioners' argument that the modifier "such" in section 136v(b) makes that clause a

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Schuver v. *E.I. Du Pont de Nemours & Co.*, 546 N.W.2d 610 (Iowa 1996); *Clubine v. Am. Cyanamid Co.*, 534 N.W.2d 385 (Iowa 1996); *Jenkins* v. *Amchem Prods, Inc.*, 886 P.2d 869 (Kan. 1994), *cert. denied*, 516 U.S. 820 (1995); *Hopkins* v. *Am. Cyanamid Co.*, 666 So. 2d 615 (La. 1996); *Hochberg* v. *Zoecon Corp.*, 657 N.E.2d 1263 (Mass. 1995); *Goeb* v. *Tharaldson*, 615 N.W.2d 800 (Minn. 2000); *Eyl* v. *Ciba-Geigy Corp.*, 650 N.W.2d 744 (Neb. 2002), *cert. denied*, 539 U.S. 958 (2003); *Pfeifer* v. *E.I. Du Pont de Nemours & Co.*, 606 N.W.2d 773 (Neb. 2000); *Davidson* v. *Velsicol Chem. Corp.*, 834 P.2d 931 (Nev. 1992), *cert. denied*, 507 U.S. 1051 (1993); *Lewis* v. *Am. Cyanamid Co.*, 715 A.2d 967 (N.J. 1998); *DiPetrillo* v. *Dow Chem. Co.*, 729 A.2d 677 (R.I. 1999); *Eide* v. *E.I. Du Pont de Nemours & Co.*, 542 N.W.2d 769 (S.D. 1996); *Quest Chem. Corp.* v. *Elam*, 898 S.W.2d 819 (Tex. 1995); *Goodwin v. Bacon*, 896 P.2d 673 (Wash. 1995); *All-Pure Chem. Co.* v. *White*, 896 P.2d 697 (Wash. 1995); *Hue* v. *Farmboy Spray Co.*, 896 P.2d 682 (Wash. 1995); *Gorton* v. *Am. Cyanamid Co.*, 533 N.W.2d 746 (Wis. 1995), *cert. denied*, 516 U.S. 1067 (1996). Although the Hawaii and Idaho Supreme Courts agree that FIFRA preempts generally, they have held that it extends only to label statements required by the EPA, not to statements voluntarily furnished by the manufacturer. *See Walker* v. *Am. Cyanamid Co.*, 948 P.2d 1123, 1128 (Idaho 1997); *Kawamata Farms*, 948 P.2d at 1080.

"subset" of section 136v(a), and thus renders "requirements" to mean something other than its plain and accepted definition. Petitioners argue that the term "requirements" must be "viewed through the lens of the 'regulation[s]' a State is permitted to issue in section 136v(a)." Pet. Br. 17. The alteration in the preceding quotation is Petitioners', and it makes all the difference. Section 136v(a) speaks of a State's authority to "regulate" and uses "the regulation" to denote the act of regulating (which cannot be pluralized), not necessarily to describe the form of positive law (of which there can be plurals). Thus, although "laws and regulations" denotes "positive enactments" when used together, *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 63 (2002), "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief." *Cipollone*, 505 U.S. at 521 (quoting *San Diego Bldg. Trades Council*, 359 U.S. at 247) (alteration in original). As Justice Breyer explains, "[t]he effects of the state agency regulation and the state tort suit are identical. To distinguish between them for pre-emption purposes would grant greater power (to set state standards 'different from, or in addition to' federal standards) to a single state jury than to state official acting through state administrative or legislative processes." *Medtronic*, 518 U.S. at 504 (Breyer, J., concurring in part and concurring in judgment).

B. Whether the EPA Actually Evaluates Product Efficacy is Irrelevant to the Interpretation of Section 136v(b), Which Turns on Whether Product Efficacy is a Requirement under FIFRA.

It is irrelevant to the analysis whether the EPA has waived data requirements for or actually evaluates product efficacy prior to registering a particular product and approving its labeling and packaging. Section 136v(b) prohibits state law requirements for labeling and packaging other than "those

required under this subchapter." Under that subchapter, section 136a(c)(5) requires the EPA to register a product if, among other things, the EPA finds that "its composition is such as to warrant the proposed claims for it" and if "it will perform its intended function without unreasonable adverse effects on the environment."

Petitioners argue that the EPA waiver of data submission for, and pre-registration evaluation of, product efficacy puts product efficacy claims outside the preemptive scope of section 136v(b). "Congress specifically amended FIFRA to eliminate a requirement that the EPA evaluate a pesticide's efficacy, so § 136v(b)'s 'requirements' do not properly encompass common-law claims addressing efficacy." Pet. Br. 29. This contention misconstrues the 1978 Amendments and the effect of the EPA waiver.

The 1978 Amendments did not change the requirements under FIFRA; they merely provided the EPA with flexibility when reviewing a product's efficacy. Under FIFRA, the EPA must register a pesticide if it finds that "its composition is such as to warrant the proposed claims for it," 7 U.S.C. § 136a(c)(5)(A), and "it will perform its intended function without unreasonable adverse effects on the environment," 7 U.S.C. § 136a(c)(5)(C). The 1978 Amendments authorized the EPA Administrator to "waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy." 7 U.S.C. §136a(c)(5). The 1978 Amendment also permitted conditional registration, as long as the pesticide otherwise complies with federal law and the registrant submits the same data required for registration under section 136a(c)(5). 7 U.S.C. § 136a(c)(7).

Although the 1978 Amendments permitted the EPA to waive "data requirements," it did not alter or rescind the general requirement that a pesticide shall be registered if the

EPA finds that "its composition is such as to warrant the proposed claims for it." 7 U.S.C. § 136a(c)(5). As a result, manufacturers still must provide efficacy data if the EPA so requests. 40 C.F.R. § 158.640(b)(1); 40 C.F.R. § 158.540. Moreover, manufacturers must report to the EPA when they learn that their products have harmed a non-target organism, such as the crop that the pesticide was designed to protect. 40 C.F.R. § 159.184(a)(1). The 1978 Amendments also left unaltered FIFRA's penalties for submitting a false or misleading label. 7 U.S.C. § 136j(a)(1)(E).

Far from rescinding the product efficacy requirement under FIFRA, Congress merely gave the EPA authority to choose whether to require data submission, and when and how to enforce the product efficacy requirement. Congress could have repealed the product efficacy requirement. That it did not do so, but instead gave EPA flexibility in enforcing the requirement, reaffirms that the product efficacy provision remains one of "those required under this subchapter." 7 U.S.C. § 136v(b). Product efficacy is therefore still within section 136v(b)'s preemptive scope, regardless of EPA's decision as to whether, when, and how to monitor compliance or enforce violations of that requirement.

Petitioners' reliance on actual EPA regulation as the hallmark of preemption compounds the error in *American Cyanamid Co.* v. *Geye*, 79 S.W.3d 21 (Tex. 2002), *cert. denied*, 539 U.S. 969 (2003). The Texas Supreme Court there focused only on the question of regulatory conflict preemption—whether there is actual EPA regulation and whether state law conflicts with such regulation. That analysis is required by the Supremacy Clause regardless of whether there is any other congressional expression of preemptive intent. FIFRA empowers the EPA to regulate pesticides; such regulations have the force of federal law. If state law conflicts with such federal regulatory requirements, then in classic conflict preemption fashion the Supremacy Clause

requires judges to enforce the federal regulation instead of the state law. *See Geier* v. *Am. Honda Motor Co.*, 529 U.S. 862, 874-75 (2000).

What the Texas Supreme Court did not consider, and what Petitioners insist that this Court ignore, is that section 136v(b) expands the scope of the federal law with which state law can conflict in two very significant ways. First, it expands the breadth of potential conflict by prohibiting any state regulation of labeling or packaging "in addition to or different from" federal requirements. 7 U.S.C. § 136v(b). Thus, any state law that is in addition to or different from federal law conflicts with section 136v(b) and therefore displaced by the Supremacy Clause. Absent this provision, supremacy only displaces those state laws that are in conflict with—not those that are in addition to or different from—a substantive federal requirement.

Second, section 136v(b) displaces state labeling requirements that differ "from those required under this subchapter." 7 U.S.C. § 136v(b). On its face, the provision expands preemption beyond conflict with actual EPA regulatory activity. All that is required under the express preemption provision is that the state imposes a requirement that is different from those required by FIFRA. So long as product efficacy remains a FIFRA requirement, state requirements relating to product efficacy are preempted. It is irrelevant whether, when or how EPA enforces this requirement; all that matters for the purposes of section 136v(b) and express preemption is that FIFRA requires it.

The Texas Supreme Court may perhaps be faulted for not considering the effect of section 136v(b). Petitioners, however, would have this Court ignore the plain text of section 136v(b) altogether. Their argument that preemption is dependent on actual EPA regulations renders section 136v(b) devoid of meaning and superfluous to the preexisting legal effect of the Supremacy Clause.

Medtronic, Inc. v. *Lohr*, 518 U.S. 504 (1996), is not to the contrary. Justice Breyer's controlling opinion there emphasized the ambiguous language of the preemption provision at issue and the existence of an agency regulation preempting only state claims that are "*divergent*" from "*specific* [federal] requirements applicable to a particular device." *Id.* at 506 (Breyer, J., concurring in part and concurring in the judgment) (emphases and alteration in original). There is no similar ambiguity in section 136v(b) and no limiting agency interpretation.

In *Medtronic*, Justice Breyer described the Medical Device Amendment's preemption provision as "highly ambiguous," and determined that such ambiguity counseled against finding that the provision preempted the tort claims at issue. *Id.* at 505. The MDA prohibits states from establishing or continuing in effect "any requirement" different from or in addition to "any requirement" applicable under federal law, and which relates to the safety or effectiveness of the device "or to any other matter included in a requirement applicable to the device" under the MDA. Describing the provision's ambiguity, Justice Breyer noted that "[t]he words 'any [state] requirement' and 'any [federal] requirement,' for example, do not tell us *which* requirements are at issue, for *every* state requirement that is not identical to even one federal requirement is 'different from, or in addition to' that single requirement." *Id.* (emphasis in original). He concluded that Congress could not have intended the MDA to have such broad preemptive reach, and that it must have expected courts to look the actions of the relevant administrative agency for preemption guidance. *Medtronic*, 518 U.S. at 505-6.

Section 136v(b) is not burdened by the same ambiguity. Section 136v(b) prohibits States from imposing or continuing in effect "any requirements for labeling and packaging" in addition to or different from "those required" under FIFRA. Unlike the MDA provision, whose plain text was virtually

limitless in its preemptive reach, Congress expressly limited FIFRA preemption to any state requirement that would affect pesticide labeling and packaging. By linking the prohibition against any state requirements for labeling or packaging to federal requirements governing the same under FIFRA, section 136v(b) provides "a clear congressional command as to preemption," *id.*, and thus eliminates any need for courts to review agency action for evidence of the federal statute's pre-emptive effect.

Similarly, Justice Breyer and every other Justice in *Medtronic* recognized the importance of the FDA's authority to issue regulations altering the scope of preemption. *Medtronic*, 518 U.S. at 496-97; *id.* at 506 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 511-12 (O'Connor, J., concurring in part and dissenting in part). Justice Stevens explained that his decision was "substantially informed by" the FDA regulations "interpreting the scope of § 360k's pre-emptive effect." *Id.* at 495.

By contrast, there is no EPA regulation altering or limiting the scope of section 136v(b) because "Congress did not give the EPA an analogous role" under FIFRA. *Etcheverry v. Tri-Ag Service, Inc.*, 22 Cal. 4th 316, 330 (2000) (citing *Oliver* v. *Reckitt & Colman, Inc.*, 12 F. Supp. 2d 1287, 1291 (M.D. Fla. 1998). Unlike the MDA, FIFRA does not permit the EPA to exempt state requirements from the statute's pre-emptive effect. In fact, FIFRA's text nowhere links section 136v(b)'s preemptive reach to the issuance of EPA regulations. The only FIFRA provision even close to a statutorily-delegated power of exemption is found in section 136p, which authorizes the EPA to grant emergency exceptions to federal and state regulatory agencies who wish to use FIFRA-registered pesticides for non-labeled uses. This power of statutory exemption relates only to FIFRA section 136j(a)(2)(G)'s otherwise strict prohibition against using any pesticide in a manner inconsistent with its label,

and it is strictly construed by the EPA. *See* 40 C.F.R. Part 166. Section 136p demonstrates that when Congress intends to grant the EPA authority to create exceptions to FIFRA's statutory scheme, it knows how to do so.

CONCLUSION

For the foregoing reasons, as well as those set forth in the Brief for Respondents, the decision below should be affirmed.

Respectfully submitted,

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DENNIS BATES, et al.,

Petitioners,

v.

DOW AGROSCIENCES LLC,

Respondent.

On Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

BRIEF FOR HERBERT SAMUEL HARRISON AS *AMICUS CURIAE* SUPPORTING PETITIONERS

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QUESTION PRESENTED

Which, if any, state law crop injury claims are preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§136-137?

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IDENTITY AND INTEREST OF *AMICUS CURIAE*

Herbert Samuel Harrison respectfully submits this brief as *amicus curiae* in this case.[1]

Harrison earned a Bachelor of Science in Professional Agriculture from Berea College in 1955 and a Masters of Agriculture from the University of Florida in 1958. He served as a Program Specialist in the United States Department of Agriculture ("UDSA") Pesticide Registration Divisions Office of Pesticide Programs ("OPP") from 1967 until 1970. In that position, he coordinated scientific and regulatory review of applications for pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). After creation of the United States Environmental Protection Agency ("EPA") by executive order in 1970, regulatory oversight of pesticides was transferred from the USDA to the EPA.

From 1970 to 1971, Harrison was the Chief of the Ecological Investigations Branch of the EPA where he developed a program to investigate the adverse effects of pesticides. In 1971, he was promoted to Chief of the Insecticide and Rodenticide Branch of the EPA where he and his staff coordinated the scientific and regulatory review of applications for pesticide registration, reregistration, amended registration, and experimental use permits. He served in that capacity for 21 years, after which he became Special Assistant to the Director, responsible for

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[1] Pursuant to Rule 37.6, *amicus curiae* discloses that no counsel for a party authored any part of this brief, nor did any person or entity other than *amicus curiae* make a monetary contribution to the preparation or submission of this brief. Letters from Petitioners and Respondent granting consent to the filing of this *amicus curiae* brief have been filed with this Court.

training the new EPA Director in the details of pesticide registration and regulation.

One of Harrison's more important duties while in the Insecticide and Rodenticide Branch was to create and edit the EPA instruction manual "General Information on Applying for Registration of Pesticides in the United States." That manual informed pesticide manufacturers and other prospective applicants how to fulfill the registration requirements of FIFRA and the Federal Food, Drug, and Cosmetic Act. That manual details the EPA pesticide registration process, regulations, and policies, and specifies the requirements for data compensation and labeling.

During his career, Harrison was awarded five EPA Bronze Medals for his work in pesticide regulation. He retired from government service in 1993, having spent the previous 27 years overseeing the registration of pesticides for the federal government. Upon his retirement and in recognition of his exceptional career service, he was awarded the EPA's Distinguished Career Gold Medal, the highest honor the Agency awards.

After retiring, Harrison began a pesticide consulting business to advise pesticide companies on the various aspects of pesticide regulation by the federal government. He has therefore kept abreast of pesticide registration developments. Due to his background and experience, he is intimately familiar with the EPA pesticide registration and label approval process, including the policy decisions involved with implementing virtually every nuance of the program. He submits this brief to demystify the pesticide registration process and to aid the Court in assessing the importance of how pesticides are registered.

SUMMARY OF THE ARGUMENT

The majority of courts to consider this issue have concluded that EPA waiver of regulation in the area of pesticide efficacy is "beside the point" and "irrelevant." By so superficially dismissing this crucial fact, those courts have exposed their fundamental lack of understanding of the EPA pesticide registration process. Analysis of the question before this Court should begin and end by recognizing the absence of EPA regulation of pesticide efficacy. Simply put, the EPA does not approve herbicide label claims regarding how well a product works. The EPA does not review whether the product actually injures the crops it was intended to assist. Without EPA review of pesticide efficacy or approval of its label-based efficacy claims, there simply is no federal regulation of pesticide efficacy. Without federal regulation, there can be no preemption.

ARGUMENT

I. Federal Pesticide Regulation Has Evolved Away From Evaluating Product Efficacy.

In its early years, pesticide regulation in this country was weak at best. Donald T. Hornstein, *Lessons from Federal Pesticide Regulation on the Paradigms and Politics of Environmental Law Reform*, 10 Yale J. on Reg. 369, 423 (1993). By the end of the 1960's, a House of Representatives subcommittee investigation concluded:

> Pesticide products had been approved for use without compliance with interdepartmental procedures for resolving safety questions; that they had been approved for uses practically certain to result in the illegal adulteration of food; that

> some labels approved for registration failed to inform users of possible hazards and provide accurate directions; that actions to cancel registered products were long delayed; that, despite completion of uncontested cancellation proceedings, hazardous products lingered in the marketing channels for years; and that conflicts of interest had clouded administrative decisions.

William H. Rodgers, Jr., *Environmental Law: Pesticides and Toxic Substances* 31 (1988) (citing H. R. REP. NO. 91-637, 91st Cong., 1st Sess. (1969)). These disclosures contributed in no small way to a 1970 government reorganization plan that stripped the United States Department of Agriculture of its authority to regulate chemical pesticides and transferred that power to the newly-established Environmental Protection Agency ("EPA"). *Id.*

Federal regulation of pesticides has grown more stringent on the EPA's watch. In 1972, Congress responded to "growing environmental and safety concerns" by "significantly strengthen[ing] FIFRA's registration and labeling standards." *Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 601 (1991). These amendments "transformed FIFRA from a labeling law into a comprehensive regulatory statute." *Id.* (quoting *Ruckelshaus v. Monsanto*, 467 U.S. 986, 991 (1984)). Under the 1972 amendments, Congress instructed the EPA to register a pesticide after evaluating its proposed label and determining that its "composition is such as to warrant the proposed claims for it." 7 U.S.C. § 136a(c)(5)(A). Pesticide manufacturers were therefore required to submit massive quantities of documents so the EPA could substantiate the claims made on a proposed label. By 1977, the requirement that the EPA evaluate and

approve pesticide efficacy[2] claims had so thoroughly overburdened the Agency that Administrator Douglas M. Costle requested that Congress eliminate the requirement that the Agency review pesticide efficacy during the registration process. H. R. REP. NO. 95-343 (1977), *reprinted in* 1978 U.S.C.C.A.N. 1974. On behalf of the EPA, Costle complained that "[t]he registration and reregistration process, which is the foundation of the program, has come to a virtual halt." H. R. REP. NO. 95-663 (1977), *reprinted in* 1978 U.S.C.C.A.N. 1991.

In 1978, Congress reacted to the EPA's predicament by amending FIFRA and permitting the EPA to forego the time-consuming and resource-intensive evaluation of product efficacy. *See* 7 U.S.C. § 136a(c)(5) ("[i]n considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy"). Congress expected this efficacy waiver authority "to be used, in particular with respect to agricultural chemicals." H. R. REP. NO. 95-663, 95th Cong., 1st Sess. 19 (1977), *reprinted in* 1978 U.S.C.C.A.N. 1992. For the past 26 years, the EPA "has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot be readily observed by the user. . . ." 40 C.F.R. §§ 158.640(b)(1); 158.540. Therefore,

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[2] As defined by the EPA, "efficacy" has two discrete components: product performance (whether the product controls the target pest) and target area phytotoxicity (whether the product harms the target crop). U.S. Inv. Br. 4, 13 (citing 40 C.F.R. §§158.540, 158.640).

although FIFRA still requires the EPA to register a pesticide after determining that "its composition is such as to warrant the proposed claims for it," the EPA no longer evaluates the efficacy of agricultural pesticides.

II. Under FIFRA, The EPA Does Not Evaluate Efficacy Of Agricultural Pesticides.

FIFRA charges the EPA with conducting four distinct registration reviews: initial registration; reregistration; experimental use permits; and special review. Fred Whitford, et al., *Pesticides and Ecological Risk Assessment* 11 (2003).[3] Initial registration of a pesticide is a two-step process and the same process applies to all applicants. *See* 7 U.S.C. § 136a(c). In the first step, the EPA decides whether a product meets the criteria for expedited review. If the product qualifies for expedited review, it reaches the second level of EPA analysis – the actual registration review – more quickly. If the product does not qualify, the manufacturer simply submits the product for conventional registration. Regardless of whether a product has qualified for expedited review, the second level of EPA review is the exact same for all products; the only difference is that products that do not qualify for expedited review have to wait longer in line.

The EPA publishes scientific testing regulations to ensure that when a product reaches the front of the line and its registration is decided by the EPA, the studies supporting its registration are complete and employ

[3] Because the pesticide at issue faced EPA scrutiny during the initial registration review process, this brief will address the EPA's waiver of efficacy data specific to that process.

premier scientific tests and methods. *See, e.g.*, 40 C.F.R. Part 160. Those regulations detail the testing required and how the studies are to be performed. *See id*. Advances in science and new experimental tools have yielded more complex and voluminous data for review, and the data commonly submitted for an initial pesticide registration frequently exceeds 10,000 pages. Whitford at 8. Those increased review responsibilities have understandably delayed the registration process and created a paradox under which the EPA is expected to conduct more intensive reviews and more quickly respond to an increased number of applications. *See id*. The EPA has attempted to alleviate the bottleneck of initial registration applications by developing several expedited review programs under which select products advance more quickly to the front of the line.

A. EPA Does Not Evaluate Efficacy When Granting Emergency Exemptions.

In emergency situations, the EPA may authorize the use of a previously unregistered pesticide. *See* 7 U.S.C. § 136p. This exemption, however, is limited in several ways. First, a federal or state agency must request the exemption. *See* 40 C.F.R. § 166.20(a). Second, the EPA must determine that emergency pest conditions exist, that is, a threat of significant economic loss, significant risk to the environment or a significant risk to endangered or threatened species or beneficial organisms. *See* 40 C.F.R. § 166.2. Third, the EPA must be able to establish a formal tolerance or limit on the amount of pesticide residues left on the treated area, especially if the pesticide residue could affect the food supply. *See* 40 C.F.R. § 166.25(a)(2). Fourth, the emergency exemption may be authorized for

"only as long as is necessary to control the pest or conditions causing the emergency." 40 C.F.R. § 166.45.

On February 24, 1999, the Texas Department of Agriculture submitted an application for an emergency exemption to permit Strongarm "to treat up to 184,000 acres of peanuts, to control broadleaf weeds" in Texas. 64 Fed. Reg. 9152 (Feb. 24, 1999). This application proposed the use of diclosulam, the active ingredient in Strongarm, a chemical that had not been previously registered by the EPA. *Id.* The EPA denied that emergency application on March 9, 1999, and Dow was forced to pursue an alternate method of expedited registration review. *See* 65 Fed. Reg. 3691, 3707 (2000) ("[t]his request was denied because adequate alternatives are available to control the weeds specified in this request.")

B. EPA Considers Product Efficacy In A Limited Manner Under The Reduced-Risk Initiative, But Not In Registering The Pesticide.

The EPA's most notable expedited review program, the "Reduced-Risk Initiative," went into effect on an interim basis in July 1993 and was finalized in September 1997. OFFICE OF PESTICIDE PROGRAMS, U.S. EVTL. PROT. AGENCY, PESTICIDE REGULATION NOTICE 97-3 § 4 (Sept. 4, 1997), available at http://www.epa.gov/oppmsd1/PR_Notices/pr97-3.html. Under this program, "lower-risk pesticide products which would result in reduced risks to human health and the environment when compared to existing alternatives" are guided through the backlog of registration applications and receive expedited review. *Id.* at § 1. Products that meet the reduced-risk criteria receive a registration decision from the EPA in an average of 14 months, compared to

38 months for conventional pesticides that do not qualify. *Id.* at § 4. During the 50 months the EPA applied the interim reduced-risk criteria, applicants sent 39 submissions to the EPA for consideration as reduced-risk pesticides. *Id.* Of that number, 22 were accepted as reduced-risk candidates[4] and 16

[4] In descending order, the factors that contributed most significantly to the EPA's decision to grant an application reduced-risk status during that 50-month period were:

- Human Health Effects
  - very low mammalian toxicity
  - toxicity generally lower than alternatives
  - displaces chemicals that pose potential human health concerns
  - reduces exposure to mixers, loaders, applicators, and reentry workers
- Non-Target Organism Effects (Birds)
  - very low toxicity to birds
  - very low toxicity to honeybees
  - significantly less toxicity/risk to birds than alternatives
  - not harmful to beneficial insects, highly selective pest impacts
- Non-Target Organism Effects (Fish)
  - very low toxicity to fish
  - less toxicity/risk to fish than alternatives
  - potential toxicity/risk to fish mitigatable
  - similar toxicity to fish as alternatives but significantly less exposure
- Groundwater
  - low potential for groundwater contamination
  - low drift, runoff potential
  - runoff mitigatable
- Lower Use Rates Than Alternatives, Fewer Applications
- Low Pest Resistance Potential
- Highly Compatible With IPM (Integrated Pest Management)
- Efficacy

Id. at § 5.

were rejected.[5] *Id.* Out of the 22 accepted reduced-risk submissions, 14 were eventually registered. *Id.*

Strongarm was not approved for expedited review under the Reduced-Risk Initiative. Stephen Schaible, the conventional reduced-risk pesticide program coordinator, advised *amicus curiae* that Strongarm was originally submitted under the Reduced-Risk Initiative, but its application was denied because it did not meet the reduced-risk criteria. The requirements of submitting efficacy information under the Reduced-Risk Initiative may be misleading, and understanding exactly what is reviewed under the Reduced-Risk Initiative and why is complicated. *Amicus curiae* was one of the initial proponents of the reduced-risk criteria and has personal experience with its practical applications. To avoid potential confusion, this brief will attempt to explain the Reduced-Risk Initiative

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[5] Also in descending order, the factors that contributed most significantly to the EPA's decision to deny an application reduced-risk status during that time were:

° Human Health Effects
- inadequate/inappropriate comparisons with alternatives
- inadequate documentation of effects
- human health risk reduction case weak

° Non-Target Organism Effects (Birds and Fish)
- toxic to birds
- toxic to fish
- risk reduction case inadequate when compared to alternatives

° Potential Groundwater Problems

° Unlikely To Displace Higher Risk Alternatives

° Lack Of Efficacy Data

° Phytotoxicity

Id. at § 5.

even though Strongarm was not approved under that process.

1. Pesticides Are Not Registered Under The Reduced-Risk Initiative.

All chemical pesticide applications ultimately face the same registration review regardless of whether they are submitted under the Reduced-Risk Initiative, a different "fast track" program in effect for registration of conventional pesticides, or the conventional registration program. 7 U.S.C. § 136a(c)(2)(A). The only benefit of the Reduced-Risk Initiative is expedited review and the possibility of accelerated registration. P.R. Notice 97-3 § 6 (noting that if the EPA "decides that a pesticide qualifies for reduced-risk status, then it will further expedite review of the remainder of the application for registration"). Regardless of the process by which an application reaches the front of the line, all applications are treated the same in the second step of EPA review – the registration process.

2. EPA Waives Efficacy Review In Registering Agricultural Pesticides.

One of the objectives of the Reduced-Risk Initiative is to displace more harmful pesticides. *See id.* at § 1. To evaluate whether consumers will purchase a new, safer product and thereby displace a more harmful one, the EPA is required to perform some review of whether the product will in fact work. *See* 57 Fed. Reg. 32140 (July 20, 1992) (stating that the "specific goal of such [reduced-risk] policies would be to encourage the registration of lower risk substitutes for existing high-risk pesticides"). In order

to decide whether an applicant qualifies for the benefits of the Reduced-Risk Initiative, the EPA requires the applicant to submit a summary of comparative performance or efficacy data – but not the supporting data itself.[6] P.R. Notice 97-3 § 7(G). The results of an applicant's efficacy studies, as represented by the summary of comparative performance data, affect whether that applicant qualifies for the benefit of expedited review under the Reduced-Risk Initiative. *See id.* at § 5. However, once the applicant passes the first step of qualifying for the Reduced-Risk Initiative, the EPA has no further use for the efficacy summaries and does not use that information in the registration process. *See id.*

As with any scientific data, much of the data that is required to be submitted for registration may be read in more than one way. The EPA requires applicants to submit data generated by standard testing against a collection of generic plants and plant families intended to generally represent plants found in the environment. *See, e.g., id.* at § 7(G). This data may, in some instances, be read to express an applicant's findings on product efficacy. *See id.* However, the EPA uses these generic tests now, as in the past, only to assess whether a new pesticide will pose an unreasonable risk to humans, non-target plants and organisms, or the environment in general. *Id.* at § 1. Although the data compiled in some of these studies may also be read to express findings as to product performance or target area phytotoxicity, the EPA does not, and due to

[6] For several years, if an applicant submitted the data supporting its summary in addition to the summary itself, the EPA's practice was to send that material back to the applicant.

insufficient funding, cannot examine those studies for that result during the registration review process.

Importantly, the EPA provides a great deal of "flexibility in requiring (or not requiring) data" and expressly offers to "waive data requirements on a case-by-case basis in response to specific written requests by applicants." 40 C.F.R. §§ 158.35, 158.45. Under the Reduced-Risk Initiative, the EPA specifically permits an applicant to substitute "reasoning as to why [required data] should not be considered in the Agency's decision" for the data itself. P.R. Notice 97-3 § 7. An applicant may, therefore, "provide a short rationale describing" the reasons it should not have to provide information required by the Reduced-Risk Initiative, including, presumably, the summary of comparative performance or efficacy data. *See id.* These provisions illustrate that the absence of information required by the Reduced-Risk Initiative may not serve as a bar to registration and even without all the required information, an applicant may still be considered for expedited review. *See id.* For that reason, applying for expedited review under the Reduced-Risk Initiative does not constitute a regulation of efficacy.

The benefits of expedited review under the Reduced-Risk Initiative are available only for those products that demonstrate a reduced risk to human health and the environment than existing alternatives. *See id.* at § 1. Requiring applicants under the Reduced-Risk Initiative to submit a summary of efficacy data but not the data themselves is the only way the resource-limited EPA can ensure that applicants can substantiate their claim to have produced a safer pesticide and their entitlement to expedited review. If the EPA did not require applicants to produce a summary of this data, then it would have no

way of knowing whether the applicant had even tested the product and would lack the ability to gauge the applicant's entitlement to the benefits of the Reduced-Risk Initiative. An applicant who claims that applying for the purely voluntary Reduced-Risk Initiative constitutes some EPA regulation of product efficacy demonstrates a lack of understanding of the Reduced-Risk Initiative and its process.

C. Efficacy Is Irrelevant In Granting "Me Too" Registrations.

Under FIFRA, the EPA may conditionally register a pesticide if it determines that "the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof or differ only in ways that would not significantly increase the risk of unreasonable adverse effects of the environment." 7 U.S.C. § 136a(c)(7)(A). This conditional registration, also called "me too" registration, is designed for products that are identical to a product previously registered by the EPA. *See* 40 C.F.R. § 152.113(b). To qualify for "me too" registration, an applicant "shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5)." *Id*. Paragraph 5 waives the requirement of submitting efficacy data. *See* 7 U.S.C. § 136a(c)(5).

When the EPA issued its March 8, 2000 registration of Strongarm, it stated that Strongarm was conditionally registered under the "me too" program. However, Strongarm's active ingredient, diclosulam, was neither identical to any currently registered pesticide, nor was it different from a currently registered pesticide only in ways that would not significantly increase the risk of unreasonable

adverse effects on the environment. That confusion prompted *amicus curiae* to contact Jim Tompkins, a Product Manager in the Herbicide Branch of the EPA's Registration Division and the signatory of Strongarm's notice of pesticide registration. Tompkins explained that Strongarm was actually registered under the "fast track" conditional registration provisions of 7 U.S.C. § 136a(c)(7)(C) and not the "me too" provisions of 7 U.S.C. § 136a(c)(7)(A). Even if Strongarm had been registered under the "me too" program, however, the EPA would not have reviewed any efficacy data Dow submitted. *See* 7 U.S.C. § 136a(c)(5).

D. EPA Waives Efficacy Review For "Fast Track" Conditional Registrations.

On March 8, 2000, Strongarm was registered under the conditional registration provisions of 7 U.S.C. § 136a(c)(7)(C). Under that statute, the EPA:

> may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this subchapter, and on other such conditions as the Administrator may prescribe.

7 U.S.C. § 136a(c)(7)(C). This "fast track" program for registering conventional pesticides is premised upon a

determination "that use of the pesticide during such period will not cause any unreasonable effects on the environment, and that use of the pesticide is in the public interest." *Id*. The conditions of Dow's registration of Strongarm required Dow to "submit and/or cite all data required for registration reregistration of your product under FIFRA sec. 3(c)(5)." Section 3(c)(5) specifically provides:

> In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 136v(c) of this title, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

7 U.S.C. § 136a(c)(5). Under this "fast track" program for registering conventional pesticides, as for all registration of chemical pesticides, the EPA has waived the evaluation of product performance and target area phytotoxicity.

E. The EPA Evaluates Efficacy In Only Two Situations, Neither Of Which Are Presented In This Case.

The EPA continues to evaluate efficacy data in two limited areas, neither of which are presented in this case. First, if the EPA considers canceling, denying, or reclassifying "registration of a pesticide product because uses of that product may cause unreasonable adverse effects on the environment," then it will initiate special review

procedures under 40 C.F.R. Part 154. 40 C.F.R. § 154.1. Because the EPA did not initiate special review proceedings against Strongarm, it did not evaluate the product's efficacy claims. Second, the EPA evaluates efficacy data in certain public health situations if it is reported that the pesticide poses some unusual risk of harm to human health or the environment. 40 C.F.R. § 158.640(b)(1). This exception applies to products such as hospital disinfectants, where a lack of efficacy might allow proliferation of microorganisms that affect public health. H. R. REP. NO. 95-663, 95th Cong., 1st Sess. 19 (1977), *reprinted in* 1978 U.S.C.C.A.N. 1992. Strongarm was not found to affect public health or pose an unusual risk of harm to human health or the environment, so the EPA was not obligated to, and in fact did not, evaluate its efficacy claims.

F. Post-Registration Reporting Of Ineffective Products Falls Short Of Efficacy Regulation.

In its invitation brief on petition for writ of certiorari, the United States argued that the EPA has not abandoned all regulation of product efficacy. Brief of Amicus Curiae the United States on Petition for a Writ of Certiorari, 13 n.2, *Bates v. Dow AgroSciences LLC*, 332 F.3d 323 (5th Cir. 2002), *cert. granted*, 124 S. Ct. 2903 (No. 03-388). The United States argued that the EPA regulates product efficacy because manufacturers must "report to EPA when they learn that their products have harmed non-target organisms such as crops or persons, if the label does not provide adequate notice of the risk of such harm." 40 C.F.R. 159.184(a)(1). Logically, however, post-registration and post-injury reporting of efficacy problems does not act as government approval of efficacy claims during the registration process. This regulation does not require the

EPA to evaluate product efficacy before the label is approved or the product is registered. For those reasons, the post-registration obligation to report efficacy complaints does not equate government evaluation of product efficacy.

III. Although Applicants May Submit It, The EPA Does Not Consider Efficacy Data In Registering Pesticides.

In 1996, the EPA explained its "procedures in approving pesticide labels relating to the efficacy of agricultural pesticides . . . to correct a misunderstanding regarding the FIFRA label approval process that is reflected in a series of court decisions concerning the preemptive effect of FIFRA." OFFICE OF PESTICIDE PROGRAMS, U.S. EVTL. PROT. AGENCY, PESTICIDE REGULATION NOTICE 96-4 § 1 (June 3, 1996), available at http://www.epa.gov/oppmsd1/PR_Notices/pr96-4.html. In that notice, the EPA's Office of Pesticide Programs stated "[b]ecause efficacy data is not reviewed as part of the registration of agricultural pesticides, it would be incorrect to contend that the label approval process involves an examination of the efficacy of the pesticide." *Id.* at 3. The EPA went a step further and clarified:

> [T]hese registration requirement should not be read as reintroducing efficacy concerns into the label approval process. *Having directly given EPA the authority to disregard efficacy issues, Congress could not have intended that, once EPA exercised this authority, the same efficiency issues would come in through the back door of the label approval process.* Under the statute and its regulations, EPA still must determine in registering a pesticide if the pesticide's label complies with FIFRA or is misbranded but, unless EPA reinstates the requirement to submit efficacy data (either generally or with regard to a particular pesticide), that compliance and misbranding inquiry will generally not extend to the evaluation of the efficacy of the pesticide.

PESTICIDE REGULATION 96-4 § 3 (emphasis added).

Under C.F.R. §§ 158.540 and 158.640(b)(1), the EPA requires all manufacturers to develop and maintain data supporting their efficacy claims. However, even the United States recognized that [g]enerally, EPA does not independently evaluate a registrant's product efficacy claims pertaining to agricultural pesticides." U.S. Inv. Br. 13 n.2. The only agricultural pesticides for which the EPA takes efficacy into account in the registration process are those that "claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user. . . ." 40 C.F.R. § 158.640(b)(1). These regulations require pesticide manufacturers to compile and maintain efficacy data, but they do not require the EPA to evaluate the efficacy data before registering the pesticide or approving the label.

Many manufacturers have argued that because they voluntarily submitted efficacy data to the EPA during the registration process, the EPA reviewed their claims of product efficacy. Plainly, that argument misses the point that the EPA is under no obligation to review these documents and lacks the resources to evaluate them. If such an argument were embraced by this Court, it would give applicants an incentive to automatically deluge the EPA with data it does not want, need, or have the ability to review. The EPA's term for such production of data, "malicious compliance," describes its view of applicants who flood it with data in an effort to gain an advantage in the registration process. Such a construction "would have the perverse effect of granting complete immunity . . . to an

industry that, in the judgment of Congress, needed more stringent regulation." *Medtronic, Inc. v. Lohr*, 513 U.S. 470, 486 (1996). Logically, therefore, it cannot be said that submission of efficacy data equates to EPA review and approval of a product's efficacy claims.

CONCLUSION

"EPA regulations define 'the domain expressly preempted.'" *Am. Cyanamid Co. v. Geye*, 79 S.W.3d 21, 24 (Tex. 2002) (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992)). In 1978, Congress waived the requirement that the EPA determine pesticide efficacy before registering that pesticide. That waiver was specifically intended for agricultural pesticides because the EPA recognized that the registrant, the user, and the USDA which insures agricultural crops are in a superior position to judge product efficacy. For more than a quarter century, the federal government has not regulated pesticide efficacy – not by registering a product, not by approving a label, and certainly not by receiving post-registration complaints. No federal agency examines whether a pesticide will control a target pest without injuring the crop to which it is applied. For those reasons, there is no federal regulation of agricultural pesticide efficacy. There can be no requirement in addition to or different from the federal regulation if there is no federal regulation. Without federal regulation, there can be no preemption.

Amicus curiae therefore urges this Court to reverse the judgment of the United States Court of Appeals for the Fifth Circuit and hold that the state law crop injury claims

pursued in this case are not preempted by the Federal Insecticide, Fungicide, and Rodenticide Act.

Respectfully submitted,

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IN THE

Supreme Court of the United States

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DENNIS BATES, *et al.*,

Petitioners,

v.

DOW AGROSCIENCES, LLC,

Respondent.

On Writ Of Certiorari to the United States Court Of Appeals For The Fifth Circuit

BRIEF OF EDWIN L. JOHNSON AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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IDENTITY AND INTEREST OF *AMICUS CURIAE*

Pursuant to Rule 37 of the Rules of this Court, Edwin L. Johnson respectfully submits this brief as *amicus curiae* to urge affirmance of the judgment below.[1]

Mr. Johnson earned a Bachelor of Engineering from Yale University in 1957, a Masters in Public Administration in 1962 and a Masters in Economics in 1964, both from Harvard University.

From 1970 to 1992 Mr. Johnson worked at the United States Environmental Protection Agency ("EPA" or the "Agency"). During 1971 and 1972, Mr. Johnson served as assistant to the Assistant Administrator for Categorical Programs (the office within EPA that, at the time, had primary responsibility for regulating pesticides), and from 1972 to 1984, Mr. Johnson held senior management positions within EPA's Office of Pesticide Programs.

From 1972 to 1975, as Director of Policy and Operations for the Office of Pesticide Programs, Mr. Johnson was responsible for strategic planning for the regulation of pesticides in the United States and was a direct deputy to the Deputy Assistant Administrator for Pesticides. From 1975 to 1984, as Deputy Assistant Administrator for Pesticides (and subsequently Director of the Office of Pesticide Programs),

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[1] The parties have submitted blanket consents to the filing of *amicus curiae* briefs. Pursuant to Rule 37.6 of the Rules of this Court, Edwin L. Johnson states that no counsel for a party has written this brief in whole or in part, and that Cheminova, Inc., a registrant of registered pesticide products sold in the United States, is the only person or entity other than *amicus curiae* and its counsel that has made a monetary contribution to the preparation and submission of this brief.

Mr. Johnson directed and managed the U.S. program for the regulation of pesticides and supervised all EPA staff responsible for the registration and reregistration of pesticides. During this period, he had primary responsibility for developing EPA policies implementing the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136, *et seq.*, and he played a leading role within the Agency in developing legislative proposals pertaining to pesticide regulation. He also represented EPA's pesticide office before Congress and before state and local governments. From 1984 to 1992, Mr. Johnson held various senior management positions within EPA, including Director of the International Issues Division from 1989 to 1992, where he had responsibility for international pesticide regulation issues.

Since leaving EPA in 1992, Mr. Johnson has worked as a consultant on global environmental and regulatory issues, particularly those relating to pesticides.

As a result of his many years of experience in senior positions within EPA's pesticide program, and his related experience since then, Johnson is intimately familiar with the 1972 and 1978 amendments to FIFRA, and EPA's regulations and policies implementing those amendments. Johnson submits this *amicus curiae* brief for two principal purposes:

(1) To help the Court understand the "efficacy data waiver" provisions that Congress added to FIFRA in the 1978 amendments to the Act; and

(2) To demonstrate that petitioners and the *amici* in support of petitioners, in particular *amicus curiae* Herbert Samuel Harrison, are incorrect in asserting that, as a result of the efficacy data waiver provisions of the 1978 amendments, EPA no longer regulates the efficacy of registered pesticide products. In this regard, it is significant that during his years

as Deputy Assistant Administrator for Pesticides and Director of the Office of Pesticide Programs at EPA, Mr. Johnson directed the program office in which Herbert S. Harrison, *amicus curiae* in support of petitioners, worked.

SUMMARY OF ARGUMENT

Under FIFRA, a person seeking to register a pesticide in the United States must demonstrate to EPA that the pesticide will not cause unreasonable adverse effects on the environment when it is used as intended.[2] *See* 7 U.S.C. § 136a(c)(5)(D). Typically, in order to make such a showing, an applicant must provide EPA with a voluminous amount of health, safety, and environmental data, and often efficacy data, in support of the applicant's pesticide registration application.

In 1978, Congress enacted several amendments to FIFRA that were intended to streamline the registration process. Among the provisions added by these amendments was the efficacy data waiver, now codified at 7 U.S.C. § 136a(c)(5). The efficacy data waiver provides EPA with discretionary authority to exempt a pesticide from the requirement to submit efficacy data as part of the registration application, if EPA determines that other mechanisms for assuring product efficacy are sufficient. *Id.*

When Congress enacted the efficacy data waiver, its sole purpose was to facilitate the process of registering pesticide

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[2] For purposes of this provision, the term "unreasonable adverse effects on the environment" is defined, in relevant part, to mean: "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb).

products, through a more efficient use of EPA and applicant resources; Congress did not intend for the efficacy data waiver to modify the express preemption provisions contained in a separate section of FIFRA, 7 U.S.C. § 136v. Moreover, even with the efficacy data waiver in place, FIFRA continues to provide EPA with robust authority to regulate the efficacy of registered pesticide products, notwithstanding the contrary suggestions of petitioners and the *amici* in support of petitioners.

ARGUMENT

I. CONGRESS ENACTED THE EFFICACY DATA WAIVER TO MAKE REGISTRATION AND REREGISTRATION MORE EFFICIENT; IT DID NOT INTEND TO MODIFY THE EXPRESS PREEMPTION PROVISIONS OF FIFRA SECTION 136v(b).

In 1972 Congress fundamentally restructured the way pesticides are regulated in the United States when it passed the Federal Environmental Pesticide Control Act ("FEPCA"), Pub. L. 92-516, 86 Stat. 973 (1972). This 1972 law made extensive changes to FIFRA and, in so doing, transformed FIFRA "from a labeling law into a comprehensive regulatory statute that will henceforth more carefully control the manufacture, distribution, and use of pesticides." H.R. Rep. No. 92-511, at 1 (1971). *See also*, *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984). In addition to expanding the scope of the federal program for pesticide regulation, the 1972 amendments also added the express preemption provision in FIFRA § 136v(b), which provides that no State shall impose "any requirements for labeling or packaging" that differ from those required under FIFRA. 7 U.S.C. § 136v(b).

The expansion of the FIFRA regulatory program that was accomplished by the 1972 amendments placed extraordinary,

and sometimes conflicting, demands on EPA's resources. In addition, in its efforts to implement the statute, EPA discovered that some of the provisions of the 1972 amendments created obstacles to the registration process that were largely unforeseen at the time the amendments were passed. *See* H.R. Rep. No. 95-663, at 18 (1977) ("It has been evident for some time . . . that there continue to be many problems that preclude effective implementation of the major changes in the law that came into effect in 1972."). As a result, by 1977 the centerpiece of the FIFRA regulatory program, the registration and reregistration process for pesticide products, "had ground to a virtual halt." S. Rep. No. 95-334, at 3 (1977).

In order to break this regulatory logjam, EPA concluded that a legislative fix would be required. Accordingly, EPA proposed to Congress several specific amendments to FIFRA which, in the Agency's view, were "critical to ending the impasse in registration...." *Id.* at 70 (Stmt. of Douglas M. Costle, Adm'r, EPA (Apr. 27, 1977)). One of the amendments that EPA proposed was the efficacy data waiver provision. This provision, along with nearly all of the other legislative changes that had been proposed by EPA, was enacted into law as part of the 1978 amendments to FIFRA. Pub. L. 95-396, 92 Stat. 819 (1978).

The efficacy data waiver authorizes EPA to waive the requirement for applicants to supply EPA with efficacy data "up-front" in support of the registration of their products. Specifically, the waiver provides that "[i]n considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's

composition is such as to warrant proposed claims of efficacy." 7 U.S.C. § 136a(c)(5).[3]

EPA sought to include the efficacy data waiver in the 1978 FIFRA amendments for one, and only one, purpose: to streamline the registration process through a more efficient and rational allocation of Agency and applicant resources. As the Agency subsequently explained:

> The decision to pursue efficacy waiver as an Agency policy stemmed from a need to reduce the amount of resources devoted to reviewing product performance so that additional effort could be devoted to the evaluation of health and safety data, and from a desire to reduce regulatory burdens in pesticide registration.

44 Fed. Reg. 27,932, 27,938 (May 11, 1979) (interim final regulations on conditional registration). *See also* S. Rep. No. 95-334, at 73 (Stmt. of Douglas M. Costle, Adm'r, EPA (Apr. 27, 1977)) ("we feel that far too much Agency time is

[3] The statutory standard for registration is set forth in § 136a(c) of FIFRA. Under that section, EPA may register a product if the Agency determines that the following criteria are satisfied:

> (A) [the product's] composition is such as to warrant the proposed claims for it;
>
> (B) its labeling and other material required to be submitted comply with the requirements of this [Act];
>
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
>
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

7 U.S.C. § 136a(c)(5).

currently being spent in reviewing efficacy data while shortages abound in the reregistration validation areas.").

From the legislative history of the 1978 amendments, it is clear that Congress had a similar goal in mind when it passed the efficacy data waiver provision. Specifically, Congress had concluded that "[t]he expenditure of resources by the Environmental Protection Agency in reviewing efficacy data is not the best use of resources …." S. Rep. No. 95-334, at 9. By enacting the data waiver, Congress expected that it would "reduce significantly the regulatory burden in the registration process…" and at the same time "permit the EPA to shift resources from the relatively less important criteria of registration to the much more critical questions of health and safety." *Id.* at 28. "This will enhance the effectiveness of the pesticide program by reducing regulatory burdens for the basic manufacturers and by providing a larger share of the EPA resources to service their registrations." *Id.*

If Congress had intended, through the 1978 amendments, to modify the express preemption provision of § 136v(b) so as to exclude efficacy claims from the scope of FIFRA preemption, it is reasonable to expect that Congress would have done so explicitly. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) (where a statute contains an express preemption provision, "there is no need to infer congressional intent to pre-empt state laws from the substantive provisions of the legislation.") (internal quotes omitted). Of course, Congress did not make such a change to the terms of § 136v(b) in the 1978 amendments. In fact, in the 1978 amendments Congress *did* make two minor changes to the wording of the preemption provision.[4] *See* Pub. L. 95-396

[4] Specifically, the provision was changed to read as follows: "Such St[illegible] shall not impose or continue in effect any requirements for labeling *or* packaging in addition to or different from those required *under* this

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§ 22, 92 Stat. 819, 835 (1978). As Congress acknowledged at the time, with these minor language changes, "the section restates section 24(b) virtually as it now reads in FIFRA." H.R. Rep. No. 95-663 at 36 (1977). The fact that Congress essentially re-enacted the FIFRA preemption provision without making any substantive changes is compelling evidence that Congress did not intend to modify the scope of FIFRA preemption in the 1978 amendments. Similarly, there is no hint in the legislative history that Congress intended the efficacy data waiver provision to alter the scope of FIFRA preemption. Instead, the legislative history of the 1978 amendments makes abundantly clear that the efficacy data waiver was "designed to facilitate registration" by streamlining the registration process to make better use of EPA and applicant resources. H.R. Rep. 95-663, at 15 (1977). This was Congress's only intent in enacting the efficacy data waiver.

II. IMPLEMENTATION OF THE EFFICACY DATA WAIVER DID NOT ELIMINATE THE REGULATION OF PRODUCT EFFICACY UNDER FIFRA

Petitioners and the *amici* in support of petitioners are wrong in asserting that because of the efficacy data waiver "there simply is no federal regulation of pesticide efficacy." Br. for *Amicus Curiae* Herbert Samuel Harrison at 3. To the contrary, FIFRA provides EPA with robust authority to regulate efficacy, even with respect to those pesticides for

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Footnote continued from previous page
subchapter." Pub. L. 95-396 § 22, 92 Stat. 819, 835 (1978) (emphasis added). The provision had previously read: "such State shall not impose or continue in effect any requirements for labeling *and* packaging in addition to or different from those required *pursuant to* this subchapter." Pub. L. 92-516 § 24, 86 Stat. 973 (emphasis added).

which the Agency does not require the up-front submission of efficacy data.

First, it is important to recognize that the efficacy data waiver in § 136a(c)(5) does not eliminate the need to develop efficacy data and submit such data to EPA in support of pesticide registration applications, nor does it eliminate or curtail the Agency's authority to regulate efficacy. Instead, the data waiver provision authorizes "the Administrator, *at his discretion*, to waive data requirements pertaining to efficacy, in considering an application for registration." S. Rep. No. 95-334, at 19-20 (emphasis added). In particular, Congress enacted this provision with the expectation that EPA would exercise this discretion to waive the up-front submission of efficacy data when "the Administrator found that some other procedure for assuring the efficacy of pesticide products appeared to be sufficient...." *Id.* at 20.

In its implementation of the efficacy data waiver, EPA has determined that, for certain types of pesticide products, up-front submission of efficacy data should not be required because other means of assuring efficacy are sufficient. For example, in its initial rulemaking pursuant to the efficacy data waiver provisions, EPA concluded that up-front submission of efficacy data for agricultural pesticides should not as a general matter be required, noting that:

> [t]he Agency's viewpoint concerning waiver of efficacy data requirements is in line with a general belief among persons in the pesticide industry, the U.S. Department of Agriculture and the agricultural community that the efficacy of agricultural pesticides can be effectively regulated by the marketplace (in conjunction with extension services and university research personnel).

44 Fed. Reg. 27,932, 27,938 (May 11, 1979).

However, even in those circumstances when other means of assuring efficacy (apart from up-front data submission) are initially presumed to be adequate (for example, with agricultural pesticides), EPA has repeatedly asserted that the Agency will act to *require* the submission of efficacy data if it turns out that these alternate means of assuring efficacy prove to be insufficient. *Id.* at 27,939 ("A request [for efficacy data] may be made for any product for which a pattern of inadequate performance has been reported."); *see also* 45 Fed. Reg. 72,948, 72,951 (Nov. 3, 1980) (proposed data guidelines for registration). Indeed, EPA has asserted that in *any* situation where the Agency has concerns regarding a product's performance, EPA may require the submission of efficacy data:

> [T]he Agency retains the right to require the submission of efficacy test data or other evidence, on a case-by-case basis, for any pesticide product, registered or proposed for registration, for which a lack of efficacy has been reported, for evaluation of product benefits when product risks are substantial, or when other factors exist which make submission of such data necessary or desirable to support the presumption that it is efficacious.

47 Fed. Reg. 53,192, 53,197 (Nov. 24, 1982) (proposed data submission requirements).

EPA has also made clear that even if up-front submission of efficacy data is waived for a pesticide, the registrant nevertheless is expected to develop and maintain data sufficient to demonstrate the product's efficacy. As stated in EPA's regulations implementing the efficacy data waiver:

> [*E*]*ach registrant* must ensure through testing that his products are efficacious when used in

> accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

40 C.F.R. § 158.640(b)(1) (2004).

Up-front submission of efficacy data is essentially a pre-market review mechanism that allows EPA to regulate product efficacy at the point in time when a registration application is filed for a product. However, FIFRA provides EPA with a number of other tools for regulating product efficacy, apart from this "pre-market" review. Thus, even in those instances where up-front submission of efficacy data has been waived, there are still several other statutory mechanisms that are available to EPA to regulate product efficacy.[5]

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[5] In this regard, it is worth noting that EPA regulates other aspects of pesticide products (apart from efficacy) without requiring up-front submission of data, or other forms of pre-market review. For example, registrants are permitted to "certify" the physical and chemical characteristics of their products, without submitting study reports or other data to support those certifications. *See* Office of Pesticide Programs, U.S. Envtl. Prot. Agency, Pesticide Registration (PR) Notice 98-1, "Self-Certification of Product Chemistry Data," *available at* http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf. Nevertheless, EPA clearly exercises regulatory authority over the physical and chemical make-up of pesticide products, and the Agency could initiate an enforcement action under § 136j(a)(1)(C) if the composition of a product were to differ from the product composition described to the Agency in connection with registration.

Similarly, EPA does not require registrants to submit copies of advertising or promotional materials for pre-market review by the Agency; nevertheless, EPA exercises jurisdiction over such promotional

Footnote continued on next page

As an example, FIFRA prohibits the sale or distribution of pesticide products that are misbranded. 7 U.S.C. § 136j(a)(1)(E). For purposes of the statute, a product is considered to be misbranded if its labeling contains any statement regarding the product that "is false or misleading in any particular" (7 U.S.C. § 136(q)(1)(A)) or if the label accompanying the product "does not contain directions for use which are necessary for effecting the purposes for which the product is intended…"(7 U.S.C. § 136(q)(1)(F)). Thus, if the efficacy of a product is insufficient to warrant labeling statements or claims (or if the labeling is otherwise misleading with respect to efficacy), the product will be deemed misbranded. Misbranded products are subject to stop sale, use, removal or seizure orders under 7 U.S.C. § 136k, and persons selling or distributing such products are subject to civil or criminal penalties, under 7 U.S.C. § 136l.

Along similar lines, under § 136d(b) of FIFRA EPA may cancel a product's registration if the Administrator finds that: (i) the product or its labeling does not comply with the Act, or (ii) the product when used in accordance with widespread practice causes "unreasonable adverse effects on the environment…." 7 U.S.C. § 136d(b). Thus, if the composition of a registered product does not warrant the claims that are made for it, in contravention of § 136a(c)(5) (in other words, if the product or its labeling does not comply with the Act), EPA could pursue cancellation of the product's registration. *See, e.g.*, 58 Fed. Reg. 41,779, 41,785-86 (Aug 5, 1993) (notice of intent to cancel based in part upon "false and misleading claims" on product labeling). Similarly, if the

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claims, and can bring an enforcement action if such claims are inconsistent with labeling and other information submitted to EPA in connection with registration. *See* 7 U.S.C. § 136j(a)(1)(B); *see also*, 40 C.F.R. Part 168, Subpart B (2004) (entitled "Advertising").

Administrator determines that the benefits of a product (which includes the product's efficacy) are significantly outweighed by the risks of the product, the Agency could pursue cancellation on the basis of the "unreasonable adverse effects" associated with the product. *Id.* at 41,779 (notice of intent to cancel "based in part on a determination that continued sale, distribution, and use of the product would cause unreasonable adverse effects on the environment. This determination is based upon data and other information showing that this product is not efficacious when used as a sterilant in accordance with its label claims.").

As the foregoing demonstrates, FIFRA provides EPA with robust authority to exercise regulatory control over the efficacy of registered pesticide products, even in those instances where up-front submission of efficacy data is not required as part of an application for registration. As EPA has explained:

> The Agency expects and believes that registrants will ensure that their products are efficacious when used in accordance with label directions and commonly accepted pest control practices. Under the statute, the registrant still has the responsibility to insure that a product satisfies its label claims. The Agency would take corrective action on a product including, when necessary, enforcement or cancellation actions, since the registrants must still comply with the law.

47 Fed. Reg. 53,192, 53,197. Consequently, the assertion that is made by petitioners and the *amici* in support of petitioners, to the effect that there is no federal regulation of pesticide efficacy, is simply erroneous.

Moreover, the current system for regulating the efficacy of registered pesticides has worked well. Shortly after the waiver was enacted, EPA warned that if the Agency were to

obtain evidence that this "experiment in public policy" was being abused by registrants ("such as a significant increase in complaints from the agricultural community, other user groups, or the general public about ineffective products") the Agency would take appropriate steps in response, including withdrawing "any or all waivers of efficacy data requirements." 44 Fed. Reg. 27,932, 27,938 (May 11, 1979). In point of fact, because of overriding business considerations, pesticide registrants continue to conduct extensive testing to ensure that their products are safe and effective when used as directed, even if those products are exempt from the up-front submission of efficacy data.[6] The fact that EPA has not had to follow through on its threat to rescind the data waiver if it were "abused" is a good indication that the current system for regulating product efficacy has worked well.[7]

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[6] One reflection of this can be seen in the numerous studies that have shown that registered pesticides are responsible for preventing billions of dollars of crop losses in the United States each year. *See, e.g.*, Leonard P. Gianessi & Sujatha Sankula, *The Value of Herbicides in U.S. Crop Production*, National Center for Food and Agric. Pol'y (Apr. 2003), *available at* http://www.ncfap.org/benefits.htm.

[7] EPA has not acted to rescind the efficacy data waiver. In 1982 the Agency proposed to *expand* the waiver to encompass certain products intended for the control of vertebrates (such as rodents). *See* 47 Fed. Reg. 40,659 (Sep. 15, 1982). This proposal was subsequently incorporated into the data requirements applicable to conditional registrations. 48 Fed. Reg. 34,000 (Jul. 26, 1983). However, shortly thereafter, EPA abandoned the proposal because the Agency concluded that, for these types of pesticides, other means of assuring efficacy (aside from up-front data submission) would not be sufficient. *See* 49 Fed. Reg. 380, 381-82 (Jan. 4, 1984).

CONCLUSION

By enacting the efficacy data waiver provisions in § 136a(c)(5), Congress did not extinguish the regulation of pesticide product efficacy under FIFRA, nor did it otherwise limit the preemptive effect of FIFRA with respect to labeling claims for efficacy. *Amicus curiae* therefore urges this Court to uphold the judgment of the United States Court of Appeals for the Fifth Circuit.

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DENNIS BATES, ET AL.,

Petitioners,

v.

DOW AGROSCIENCES LLC,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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INTRODUCTION AND INTEREST OF AMICI[1]

This brief addresses the issue of whether the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.*, preempts state damages actions arising out of personal injuries caused by exposure to federally registered pesticides. Amici are non-profit organizations dedicated to protecting individuals from harm relating to dangerous consumer products, including pesticides, and many have participated in regulatory proceedings concerning federal pesticide registration. Amici believe that FIFRA and state damages actions complement one another in a constructive way that strengthens the public health protection derived from pesticide regulation.

Natural Resources Defense Council is an environmental organization with more than 465,000 members nationwide. Its membership and staff of scientists, lawyers, and other environmental specialists have a longstanding interest in improving the regulation of pesticides and other toxic chemical residues in food, air, and water. NRDC has actively participated in the development, enforcement, and reform of pesticide laws and pesticide regulation for over two decades.

Public Citizen is an advocacy, lobbying, and litigating organization with 160,000 members nationwide. It has a longstanding interest in limiting the reach of the federal preemption doctrine to situations in which Congress clearly intends to oust state law in order to serve important federal objectives. Public Citizen's lawyers have represented parties and amici before this Court in many cases that posed the

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[1]In blanket letters of consent filed with the Clerk, the parties have consented to the filing of amicus briefs in this case. Pursuant to this Court's Rule 37.6, amici state that this brief was not authored in whole or in part by counsel for a party and that no one other than amici made a monetary contribution to the preparation or submission of this brief.

question whether federal law preempts state-law remedies intended to compensate those harmed by tortious conduct.

Trial Lawyers for Public Justice is a national public interest law firm dedicated to pursuing justice for the victims of corporate and governmental abuses. It seeks to ensure that tort law fully serves its dual purposes – compensating those injured by wrongful conduct and deterring similar conduct in the future. TLPJ is gravely concerned that, if the tort system is closed to innocent victims of improperly labeled pesticides through application of the preemption doctrine in this case, neither of these purposes will be served.

The Sierra Club is an environmental organization with over 700,000 members nationwide. It was one of the first organizations to advocate for laws protecting human health, wildlife, and the environment from the damage caused by pesticides.

Beyond Pesticides/National Coalition Against the Misuse of Pesticides has approximately 1,200 members nationwide. It promotes public and worker protection from pesticide hazards and the adoption of alternative pest management strategies that reduce or eliminate dependency on toxic chemicals. Beyond Pesticides has been an active participant in the regulatory process under FIFRA since its founding in 1981.

Defenders of Wildlife has over 450,000 members and supporters nationwide. It is dedicated to the protection of all native wild animals and plants in their natural communities. Defenders' programs focus on three serious threats to the planet: the accelerating rate of extinction of species; the associated loss of biodiversity; and the alteration and destruction of habitat.

Physicians for Social Responsibility is a national organization whose 30,000 members are physicians, other healthcare and public health professionals, and citizens concerned about threats to human health. It educates the medical community and the public about the links between

environmental exposures and human health and promotes preventive, precautionary policy solutions to protect public health. PSR has been an active participant in the regulatory proceedings under FIFRA.

The Farmworker Justice Fund, Inc. is an advocacy and education organization based in Washington, D.C. Its purpose is to empower migrant and seasonal farmworkers to improve their wages, working conditions, occupational safety, health, immigration status, and access to justice through litigation, advocacy, public awareness, capacity building, coalition building, and support for union organizing. For more than two decades, FJF has fought for improved protections for farmworkers and their families exposed to pesticides at home and on the job.

SUMMARY OF ARGUMENT

FIFRA charges registrants with ensuring that their pesticides will not have unreasonable adverse health and environmental effects and with writing pesticide labels that achieve this result. Once the Environmental Protection Agency ("EPA") approves a pesticide use under this standard, the pesticide may then be sold and used in the United States.

EPA's past approval of a pesticide label, however, affords no guarantee that the pesticide use will comply with FIFRA's "unreasonable adverse effects" standard over time as regulatory standards change and new evidence emerges. FIFRA commands the registrant to keep EPA apprised of any information documenting adverse effects from a pesticide use and to seek changes in the registration and EPA-approved label when warranted by such new information or changing conditions. A pesticide is misbranded and subject to FIFRA enforcement measures if its label, even if federally approved, does not provide adequate health and environmental protection. This potential misbranding liability evinces Congress's intent that FIFRA would be a fluid scheme, obligating registrants to

provide EPA adverse effects information and to update their labels to reflect such information and current standards.

Common-law liability similarly imposes obligations to ensure that product design and labeling will avoid unreasonable adverse health and environmental effects. State damages actions can identify shortcomings in previously approved FIFRA registrations and labels and prompt registrants to remain vigilant in ensuring that their products can be used without harming human health and the environment. Such actions create an incentive to avoid unreasonable harm and serve as a catalyst for registrants to modify their pesticide products and labels when warranted by evolving legal standards, emerging science, and evidence of harm from existing uses.

ARGUMENT

I. FIFRA ESTABLISHES A FLUID REGULATORY SCHEME IN WHICH PESTICIDE REGISTRATIONS AND EPA-APPROVED LABELS MUST CHANGE TO CONFORM TO UPGRADED HEALTH AND ENVIRONMENTAL STANDARDS AND NEW EVIDENCE OF ENVIRONMENTAL AND SAFETY RISKS.

A. FIFRA Imposes a Duty on Pesticide Registrants to Avoid Unreasonable Adverse Health and Environmental Effects At All Times.

Congress enacted FIFRA in 1947 to protect farmers from adulterated and ineffective pesticides. For over three decades, FIFRA had no health or environmental protections. In 1972 in the wake of Rachel Carson's *Silent Spring* and the controversy over DDT, Congress adopted a sweeping overhaul of FIFRA that made health and environmental protections its centerpiece. *See* Pub. L. No. 92-516, 86 Stat. 996 (1972); H.R. Rep. No. 511, 92d Cong., 1st Sess. (1971). The amended

FIFRA required EPA to determine allowable pesticide use based on the increasing body of scientific evidence indicating that pesticides pose risks to human health and the environment.

As amended, FIFRA establishes a federal-state partnership with minimum federal standards that states and their subdivisions can supplement and make more stringent but cannot undercut. *See* 7 U.S.C. § 136v(a). A pesticide may generally not be sold or used in the United States unless it has an EPA registration for a specific use of the pesticide. *Id.* § 136a(a). EPA registers a pesticide upon determining that the labeling complies with FIFRA's requirements, that composition claims are warranted, that the pesticide will perform its intended function, *and* that the pesticide use will not cause unreasonable adverse effects on health or the environment. *Id.* § 136a(c)(5).

EPA must classify pesticides as general or restricted use pesticides, depending on the risks posed to human health and the environment. Where necessary to prevent unreasonable adverse health or environmental effects, EPA must classify a pesticide as restricted use. *Id.* § 136a(d)(1)(C). Restricted use pesticides are subject to additional regulatory restrictions, particularly concerning application of the pesticide. *Id.*

FIFRA requires a person seeking to register a pesticide to demonstrate that the proposed pesticide meets FIFRA's standards. *Id.* §§ 136a(a), (c). The proponent bears the burden of proof and must present sufficient supporting scientific evidence of the pesticide's safety and impact on health and the environment. 40 C.F.R. § 152.50(f)(3). EPA has established standards for the data required to support a pesticide registration. *See generally* 40 C.F.R. Part 152. The company seeking the registration (the "registrant") generates and submits the scientific studies on which EPA will base its determination. *Id.*

An EPA registration is a license to market and use a pesticide that conforms to a specified formulation and the use restrictions approved by EPA. The use restrictions are set out

on the EPA-approved label affixed to the product as it moves through interstate commerce. A pesticide may not be used in a manner inconsistent with the label. 7 U.S.C. § 136j(a)(2)(G).

The 1972 amendments left existing registrations in place until the registrants submitted newly required data and, based on its assessment of such data, EPA either canceled or reregistered the pesticide uses with modifications to meet the new health and environmental standard. As of 1986, EPA had reregistered *none* of the 50,000 pesticides subject to reregistration, and had completed its reassessment of *none* of the 600 pre-1972 active pesticide ingredients. General Accounting Office, *Pesticides: EPA's Formidable Task to Assess and Regulate Their Risks* at 3 (1986).

Congress amended FIFRA in 1988 and again in 1996 to impose deadlines on the reregistration process. Under the statutory timetable, EPA is not scheduled to complete the reregistration of all the old pesticides until fiscal year 2008. *See* 7 U.S.C. § 136a-1(g)(2)(A)(ii). Even when this initial reregistration process is complete, EPA will regularly need to revisit existing reregistrations to assess new data. It is common for a registration to identify gaps in data that the registrant must fill over time. For example, in 2000, EPA issued a conditional registration for Strongarm, the pesticide at issue in this case, that required the registrant to submit neurotoxicity, mutagenicity, and residue chemistry studies. http://www.epa.gov/opprd001/factsheets/diclosulam.pdf. While the studies were due in 2001, EPA has yet to complete its assessment and make revisions to the conditional registration. Similarly, under the 1996 Food Quality Protection Act, EPA must assess a food-use pesticide's potential to cause endocrine disruption effects and the cumulative effects of exposures to pesticides that have a common mechanism of toxicity, 21 U.S.C. § 3462(b)(2)(D)(v) & (viii), yet EPA is still in the process of developing protocols for assessing such effects. 67 Fed. Reg. 79,611 (Dec. 30, 2002) (requesting comment on EPA's proposed approach for screening for an

initial group of chemicals for effects on endocrine system). Likewise, EPA typically reregisters pesticides without first engaging in required consultations with the Fish and Wildlife Service and National Marine Fisheries Service to determine whether the pesticide use will jeopardize the survival of endangered species, as required under the Endangered Species Act ("ESA"), 16 U.S.C. § 1536(a)(2). *See Washington Toxics Coalition v. EPA*, No. C01-132C, Orders (W.D. Wash. July 2, 2002 & Aug. 8, 2003) (declaring EPA in violation of ESA for failing to consult on its pesticide registrations' impacts on threatened and endangered salmon and ordering injunctive relief). Once EPA completes the ESA consultations, it will need to make changes to the registrations required to ensure that the pesticides will not cause jeopardy to endangered species' survival.

Because EPA depends almost entirely on manufacturer submissions, and EPA does not itself conduct testing on the pesticides' health and environmental effects, FIFRA imposes stringent and continuing obligations on registrants to submit complete, up-to-date information to EPA. First, a registrant may not knowingly falsify any part of an application for registration or other information required to be submitted under FIFRA and may not make any false or misleading statement or representation in a pesticide's labeling. 7 U.S.C. §§ 136j(a)(1)(E), 136j(a)(2)(C) & (M); 136(q)(1)(A). Second, even after EPA issues a registration based on the registrant's submissions, the registrant has an ongoing obligation to provide EPA with all factual information that they have regarding unreasonable adverse health and environmental effects. *Id.* § 136d(a)(2); 40 C.F.R. Part 159.

Third, and of critical importance, registrants have a continuing obligation to ensure that the registration and label complies with FIFRA's requirements. *Id.* §§ 136j(a)(1)(E), 136(q). Under FIFRA, "the burden is on the registrant to establish that continued registration poses no safety threat." *Environmental Defense Fund v. EPA*, 510 F.2d 1292, 1302

(D.C. Cir. 1975).

To satisfy this burden, registrants must make changes to the registration and labels whenever necessary to protect health and the environment. In turn, FIFRA mandates that "the registration *shall* be amended to reflect such change if the Administrator determines that the change will not violate any provision of this subchapter." 7 U.S.C. § 136a(f)(1) (emphasis added).

If EPA determines that the pesticide registration does not comply with FIFRA, EPA may commence administrative proceedings to cancel the pesticide's registration. *Id.* § 136d(b). EPA may also seize or bar the use or sale of pesticides that violate FIFRA. *Id.* §§ 136j & 136k; *see also id.* § 136*l* (authorizing civil and criminal penalties for FIFRA violations). None of these mechanisms for enforcing FIFRA provides compensation to individuals who suffer injuries as a result of FIFRA violations; nor does any other federal cause of action provide such compensation. Traditional state-law damages actions thus have historically provided the only means for compensating people who have been injured by unsafe or mislabeled pesticides.

Because cancellation proceedings are time-consuming and expensive, EPA rarely brings them to compel label changes. Rather, EPA leaves most use and label changes to its ongoing process of reregistering pesticides. However, as noted above, EPA has yet to reregister thousands of pesticides that were initially registered before Congress, in 1972, imposed stringent data requirements pertaining to human health and environmental harm. Because EPA waits until the culmination of the reregistration process to impose most product and label changes on the registrant, EPA is not currently ensuring that the pesticide registrations and labels for thousands of pesticides comply with FIFRA. EPA's reregistration backlog makes it all the more critical that pesticide registrants have strong incentives to comply with their obligation to make whatever product and label changes are necessary to meet FIFRA's

requirements. For this reason, the Assistant Administrator of EPA for Pesticides and Toxic Substances took the position in 1994 that:

> After reviewing the legal framework and the policy considerations, I conclude that EPA would clearly prefer the legal interpretation that FIFRA does not preempt state tort actions.. . . With the limited government resources available to regulate a growing number of pesticide products, we believe that tort litigation can be an effective tool and ally to the regulatory process. If tort actions are not preempted by FIFRA, manufacturers' concern about possible tort liability may well lead them to take additional steps to provide users with information about their products. Such information could, in turn, enable users to choose and use pesticides in ways that are safer for themselves, others, and the environment.

Letter from Lynn R. Goldman, Assistant Administrator for Pesticides and Toxic Substances (Jan. 7, 1994) (reproduced in addendum to this brief).

B. FIFRA Imposes an Ongoing Obligation on Registrants To Draft Pesticide Labels That Adequately Protect Health and The Environment.

Unlike federal statutes governing cigarettes and smokeless tobacco, FIFRA does not mandate the precise wording for pesticide labels, *see* 15 U.S.C. §§ 1333, 4402(a)(1). Nor do EPA's regulations dictate the specific language to be used for the bulk of each label, as some regulations do. *See* 21 C.F.R. § 801.430(c) (specific tampon warning).

Rather, FIFRA leaves the drafting of the label to the registrant. 7 U.S.C. § 136a(c)(1)(C); 40 C.F.R. § 152.50(e). It

charges the registrant, not the government, with devising pesticide labels that convey adequate information to prevent "unreasonable adverse effects" to health and the environment. As a result, labels for similar pesticides produced and marketed by different registrants may differ significantly from one another. Such differences are permissible as long as the registrant writes a label that ensures against "unreasonable adverse effects." As EPA has made clear, "[t]he registrant must take responsibility for quality control of the product's composition and for adequate labeling describing the product, its hazards and uses." 53 Fed. Reg. 15,952 (May 4, 1988).

FIFRA and EPA's regulations establish certain minimum requirements for pesticide labels, such as the inclusion of certain terms to reflect acute poison risks. Inclusion of such FIFRA mandated statements, however, does not satisfy the registrant's FIFRA obligations. The label must also contain directions for use that guard against unreasonable adverse effects. Moreover, FIFRA allows labels to contain information that goes beyond those requirements, and EPA never assesses whether a label complies with other legal obligations.

A registrant has a duty to submit revised labels for EPA approval whenever the existing label falls short of meeting FIFRA's requirements. Many label revisions require *only* EPA notification, not agency approval, 40 C.F.R. § 152.46(a), and some revisions, such as changes in nonmandatory label statements, additions required by other federal laws, or changes in the label format, do not even require EPA notification. 40 C.F.R. § 152.46; *see also id.* §§ 152.130(b) & (c), 152.132(d)(5). As such, it is the registrant who decides that a label change is necessary and who drafts a revised label. EPA must allow the label change to be made unless it would violate FIFRA. 7 U.S.C. § 136a(c)(5).

A pesticide is misbranded if, notwithstanding EPA's registration of the pesticide and acceptance of the label, it fails to contain whatever additional warnings are necessary to

protect against unreasonable adverse health and environmental effects. *Id.* § 136(q)(1)(F)-(G). The fact that EPA has approved a label is no defense to a claim under FIFRA that the product is misbranded. *Id.* §§ 136(q)(1)(A), 136a(f)(2). In other words, the fact that a pesticide label has been approved does not immunize the registrant from liability for violating its FIFRA obligations. Indeed, EPA has recognized that "[f]or liability reasons, companies often voluntarily provide additional information on the label, particularly in the area of precautionary statements." 49 Fed. Reg. 37,960, 37,971 (Sept. 26, 1984). Nothing in FIFRA or EPA's regulations prohibits including such label warnings, provided that they do not violate any specific requirement imposed by FIFRA or its implementing regulations. *Id.*

C. FIFRA's Preemption Provision

FIFRA contains a section, entitled "Authority of States," which affirms state authority to supplement federal pesticide regulation:

> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

7 U.S.C. § 136v(a). Through this provision, Congress expressly left room for state regulation that affords more, but not less, health and environmental protection.

Immediately following this subsection is FIFRA's label preemption provision, which provides:

> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

Id. § 136v(b). This provision does not pertain to state damages actions at all, since "[s]uch State" refers back to the preceding

provision, which refers to states that "regulate" pesticide sale or use through "regulation." The reference to state requirements is therefore limited to regulations, which are generally understood to embody statutes or legislative-type rules. *See Cipollone v. Liggett*, 505 U.S. 504, 519, 523 (1992) (preemption provision's reference to "regulation" most naturally refers to positive enactments of regulatory bodies, not to common law damages remedies). Even if it is construed to apply to state damages actions, the preemption provision is limited to those labeling or packaging requirements that are "in addition to or different from" those required under FIFRA. The linchpin would, therefore, be whether state law obligations create duties in addition to or different from FIFRA's unreasonable adverse effects standard. As explained below, state common-law obligations generally do no such thing.

None of FIFRA's state authority provisions directly addresses the viability of state damage actions. The only explicit legislative discussion of FIFRA's preemptive effect on state damage actions came in 1982 during congressional debates over an amendment that would have provided federal injunctive relief for persons injured by pesticides. In the course of these debates, several House Members and EPA indicated their belief that state tort remedies were generally available. 128 Cong. Rec. 20,498, 20,504 (1982) (Representative Wampler stated he knew of no case "where a private citizen had not been able to sue in state courts for redress of grievances."); *id.* at 20,502 (Representative Panetta explained that the amendment would provide federal injunctive relief but leave individuals harmed by pesticides state court remedies for money damages); *id.* at 20,500 (Representative Thomas explained that, without the amendment, individuals would merely have "State rights in terms of suing for damages, negligence, nuisance"); Testimony of John A. Todhunter, *Reauthorization of the Federal Insecticide, Fungicide, and Rodenticide Act: Hearings on S. 2245, S. 2620 and S. 2621 Before the Senate Committee on Agriculture, Nutrition and*

Forestry, 97th Cong., 2d Sess. (1982) (testimony of EPA official explaining that EPA believed the amendment was unnecessary because "it is something we feel people have under existing laws other than FIFRA and our preference would be not to see FIFRA cluttered up with additional amendments putting those particular things in FIFRA").[2] Therefore, the only evidence directly on point reveals that Congress believed that individuals harmed by pesticides continue to have recourse to state damage actions under the FIFRA scheme.

II. STATE COMMON-LAW OBLIGATIONS PARALLEL MANUFACTURERS' DUTIES UNDER FIFRA, ENCOURAGE SPEEDIER FIFRA COMPLIANCE, AND PROMOTE FIFRA'S GOAL OF PROTECTING HEALTH AND THE ENVIRONMENT.

In *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597 (1991), this Court held that FIFRA does not preempt local regulation of pesticide use. Although the Court stated that "the 1972 amendments turned FIFRA into a 'comprehensive regulatory statute,'" *id.* at 613 (quoting *Ruckelshaus v. Monsanto*, 467 U.S. 986, 991 (1984)), it recognized that "FIFRA nonetheless leaves substantial portions of the field vacant . . .. FIFRA nowhere seeks to establish an affirmative permit scheme for the actual use of pesticides. It certainly does not equate registration and labeling requirements with a general approval to apply pesticides throughout the Nation without regard to regional and local factors like climate, population, geography, and water supply." *Id.* at 613-14. The Court concluded that FIFRA's specific grant of authority to states to

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[2]The House passed the amendment offered by Representative Panetta, but the substitute measure that passed the Senate Forestry and Agriculture Committee did not contain that amendment. S. Rep. No. 511, 97th Cong., 2d Sess. (1982).

regulate pesticide sale and use "acts to ensure that the States could continue to regulate use and sales even where, such as with regard to the banning of mislabeled products, a narrow pre-emptive overlap might occur." *Id.* at 614.

Just as local pesticide regulation may complement and fill gaps in federal regulation under FIFRA, state damages actions likewise further the state's preserved authority to regulate pesticide sale and use. The common-law duty to warn users and the public of pesticide hazards reinforces the registrants' duty to ensure that their labels guard against unreasonable adverse effects. Moreover, some state legal obligations also buttress the registrants' duties to provide EPA up-to-date information about pesticide hazards so that EPA can ensure that previously issued registrations continue to protect the public.

A. FIFRA's Express Recognition of State Authority to Regulate Pesticide Sale and Use Supports the Availability of State Damages Actions That Would Lead to Sale and Use Restrictions.

Under 7 U.S.C. § 136v(a), a state may ban the sale or use of a federally registered pesticide or may impose restrictions on its use beyond what EPA has imposed. *See* S. Rep. No. 92-970, 92d Cong., 2d Sess. (1972), *reprinted in* 1972 U.S.C.C.A.N. 4092, 4111-12 ("Local governments could, however, prohibit or restrict the sale or use of pesticides within their jurisdiction."). For example, the States of Massachusetts and Wisconsin imposed restrictions on the use of daminozide on apples after EPA determined that it was a carcinogen, but before EPA took action to restrict its use. *See* Mass. Ann. Laws ch. 94, § 192; Wis. Stat. § 94.707(1m). Similarly, states have banned or restricted the use of other pesticides that EPA had permitted to be used. *See, e.g.*, Cal. Health & Safety Code § 111246 (lindane); 3 Cal. Code. Reg. § 6400 (restricted use

pesticides); Wash. Admin. Code 16-228-1231(e) (restricting the use of numerous pesticides to protect groundwater); Iowa Code Ann. § 206.32 (chlordane); Md. Code Ann. Agric. § 5-210.5 (chlordane, heptachlor, aldrin and dieldrin); Minn. Stat. § 18B.115 (chlordane and heptachlor); Wis. Stat. § 94.707(a)-(b) (2-4-5 trichlorophenoxyacetic acid and silvex).

State authority to ban or restrict pesticide use in a regulatory capacity is similar to many types of state damages actions. Although a regulatory ban directly prevents harm before the fact, state damages actions allow individuals harmed by pesticide use to sue for damages to compensate for their losses. The underlying legal duty in such a case may require the pesticide manufacturer to avoid designing, marketing, or selling a pesticide for a use that causes the same type of harm an affirmative state regulation may seek to prevent. If a state can affirmatively ban a pesticide to prevent harm to its citizens, as it can under the FIFRA scheme, it also can allow its citizens to enforce and seek redress for violations of legal duties in lawsuits that may indirectly produce the same result. *See Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185 (1988) ("The effects of direct regulation on the operation of federal projects are significantly more intrusive than the incidental regulatory effects of such an additional award provision. Appellant may choose to disregard Ohio safety regulations and simply pay an additional workers' compensation award if an employee's injury is caused by a safety violation. We believe Congress may reasonably determine that incidental regulatory pressure is acceptable, whereas direct regulatory authority is not.") (citation omitted).

An apt example is provided by litigation over the pesticide phosdrin, a highly toxic nerve-agent, which caused acute poisonings of farmworkers. In the summer of 1993, Amvac Corp. marketed phosdrin for the first time in Washington state, even though more than 600 suspected poisonings of workers, including three deaths, were reported in California from 1982 through 1989. Amvac had acknowledged

that the existing FIFRA registration and label did not adequately protect workers, EPA had directed Amvac to develop and implement restrictions on phosdrin use to protect workers, and California had already imposed some such restrictions. Upon finding the FIFRA requirements inadequate, the Washington Department of Agriculture adopted an emergency regulation requiring worker training, wind restrictions to lessen drift, and safeguards to protect workers who mix and apply the pesticide. Tragically, however, throughout the summer of 1993, 29 workers reported acute pesticide poisoning from exposure to phosdrin. The Washington Department of Agriculture banned all phosdrin use before the end of the summer to stop the stream of worker poisoning incidents. The following year, EPA, which had been conducting a review of phosdrin's worker impacts, concluded that phosdrin caused unreasonable adverse effects to workers. In the summer of 1994, shortly after EPA announced its intent to take steps to suspend phosdrin's registration, Amvac requested a voluntary cancellation of its FIFRA registration for phosdrin. 59 Fed. Reg. 38,973 (August 1, 1994); 60 Fed. Reg. 17,357 (April 5, 1995).

The workers became casualties of EPA's delays in canceling registrations of pesticides that do not meet FIFRA's unreasonable adverse effects standard. Three of the workers sued both Amvac and the distributor for marketing and distributing a defectively designed product. The Washington Supreme Court upheld their right to bring such a claim under state law, *Ruiz-Guzman v. Amvac Chemical Corp.*, 7 P.3d 795 (Wash. 2000), and the Ninth Circuit held that FIFRA did not preempt the workers' design defect claims. *Ruiz-Guzman v. Amvac Chemical Corp.*, 2000 WL 1763212 (9th Cir. 2000). Ultimately, the cases resulted in a settlement. The injured workers' ability to seek damages promoted FIFRA's purpose of protecting workers against unreasonable adverse effects from pesticides.

A similar situation occurred in connection with a rat

poison that tasted sweet and looked like candy. Although the label cautioned to keep the rat poison out of reach of children and that the poison might be harmful if swallowed, a nine-year-old boy ate some of the poison when he found it at a boys' club and ultimately died as a result. A jury awarded his family compensatory and punitive damages upon finding that the registrant withheld adverse incidents of human exposure from EPA and that the product could have been designed with a bittering agent to avoid being mistaken for candy and with a substance that would induce vomiting. The Georgia Supreme Court held that FIFRA preempted the failure-to-warn claim and remanded the design defect claim for a new trial under a newly announced risk-utility test. *Banks v. ICI Americas, Inc.*, 450 S.E.2d 671, 673 (Ga. 1994).

State damages actions play a particularly important role in promoting FIFRA's health and safety goals given the backlog in EPA reregistrations discussed above. And EPA is continually upgrading registration requirements to address emerging evidence of adverse effects. For example, for years, workers have been exposed to harmful and sometimes lethal doses of pesticides when they re-enter sprayed areas. Although pesticide registrations establish prohibitions on worker re-entry during specified periods, the specified periods have often proved to be insufficient to protect the workers from acute poisonings. As part of its implementation of a worker protection standard promulgated in 1992, 40 C.F.R. § 170.112, and its reregistration process, EPA is reviewing and expanding the re-entry periods. However, workers have been subjected to excessive exposures to acutely toxic pesticides in the meantime and rely on state-law compensation systems to make them whole.

Not only is the reregistration process plagued by delay, but EPA is sometimes unwilling to take action that would constrain certain pesticide uses, particularly where the scientific basis for the constraint is questioned by the registrant. For example, in 1984, after finding that arsenic-treated wood

products posed excessive cancer and birth defect risks, EPA announced its intent to cancel registrations of arsenic products used to treat wood unless consumer warnings and precautionary information were provided to wholesalers, distributors, and retailers to be passed along to consumers. 49 Fed. Reg. 28,666 (July 13, 1984). Two years later, EPA accepted a voluntary industry-sponsored consumer awareness program, in lieu of mandatory warnings. 52 Fed. Reg. 1334 (Jan. 10, 1986). After acceptance of this voluntary program, reports of people being poisoned and playground structures and decks being contaminated by arsenic-treated wood continued to surface, precipitating dozens of lawsuits against the makers and distributors of arsenic-treated wood. Liptak, "The Poison is Arsenic, and the Suspect Wood," *New York Times*, at A1, June 26, 2002; Environmental Working Group and Healthy Building Network, *Poisoned Playgrounds* 13-14 (2001). In response, the industry and EPA agreed to a phase-out of arsenic-treated wood for residential uses. 67 Fed. Reg. 8244 (Feb. 22, 2002); http://www.epa.gov/pesticides/factsheets/chemicals/cca_transition.htm.

State damages actions, like those seeking redress for poisonings and contamination from arsenic-treated wood, promote FIFRA's goal of preventing adverse health and environmental effects from pesticide use. Since FIFRA expressly authorizes states to regulate pesticide sale and use directly, it must also be read to preserve state damages actions that indirectly further this goal.

B. Failure-to-Warn Actions Reinforce the Registrant's Duties to Ensure that Pesticide Labels Meet FIFRA's Standards.

If FIFRA preemption extends to state damages actions at all, it preempts only those failure-to-warn claims that require a label that is "in addition to or different from" that required under FIFRA. 7 U.S.C. § 136v(b). Since FIFRA requires

labels to ensure that the pesticide use will not cause unreasonable adverse health or environmental effects, state failure-to-warn duties reinforce FIFRA's label requirements.

Few, if any, state tort claims allege that manufacturers should have required different label warnings from those required under FIFRA, because most state duty-to-warn obligations are subsumed within FIFRA's unreasonable adverse effects standard and its misbranding mandate, *i.e.*, they challenge a failure to provide sufficient warnings to prevent unreasonable adverse effects. Where plaintiffs are seeking redress for a failure to relay critical warnings to the public, state damage actions do not impose any labeling requirements that are "in addition to or different from those required under" FIFRA. *Id.* Instead, they provide a means for individuals who are harmed by misbranded pesticides to obtain compensation for that harm. The remedial measures that the registrant would take to avoid such liability would either consist of label changes that would be required under FIFRA in any event, or other means of conveying information — such as pamphlets, advertisements, and notices in publications — which are not subject to FIFRA's labeling requirements. The common-law duties on which those allegations were based thus mimic the manufacturer's duties under FIFRA, which places the burden of testing, identifying, and labeling as to risks to people and the environment on the registrant.

Thus, the plaintiffs' claims arising from pesticide-related injuries are based on state-law duties that parallel requirements imposed under FIFRA. Like the "parallel" state claims held not preempted by the federal Medical Device Amendments, *see Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496-97 (1996), they are not "in addition to or different from" FIFRA's requirements within the meaning of 7 U.S.C. § 136v(b), and, therefore, are not preempted.

In *Jenkins v. James B. Day & Co.*, 634 N.E.2d 998 (Ohio 1994), the Ohio Supreme Court reached the same conclusion with respect to the Federal Hazardous Substances

Act ("FHSA"), which preempts state cautionary labeling requirements that are not identical to applicable federal labeling requirements. 15 U.S.C. § 1261. The court held that FHSA labeling requirements do not preempt state duty-to-warn claims because they are identical; both require the manufacturer to design product labels that "protect against the [] risk of illness or injury." 634 N.E.2d at 1002.

The possibility of state tort liability creates additional incentives for manufacturers to ensure that their labels contain the most complete and accurate information available to protect health and the environment consistent with FIFRA. It is particularly important to maintain strong incentives for registrants to make necessary labeling changes, given that it will be many years before EPA completes its assessment of existing labels as part of the pesticide reregistration process and that EPA will continue to assess and require revised labels after that. A contrary reading would permit a manufacturer, who knew of dangers from use of the pesticide as directed on the label, to refrain from informing EPA of needed label changes and then to hide behind the very label it knew to be inadequate. Such a result was never contemplated by Congress and should not be countenanced by the courts.

It makes sense for Congress to preempt state regulatory labeling requirements, while allowing state damage actions that challenge the adequacy of pesticide warnings. In order to guard against duplicative label approval schemes burdening interstate commerce, Congress sought to ensure that manufacturers would have one label nationwide, rather than different ones in each state. A reading of 7 U.S.C. § 136v(b) to encompass state label regulations, but not damage actions, accomplishes that result. No state can establish a label approval scheme. Since the registrant must use an EPA-approved label, pesticide labels for particular products will be uniform throughout the United States.

Indeed, this Court has repeatedly noted, in rejecting preemption of state damages claims, that Congress can

rationally preempt state regulatory efforts that conflict with the federal regulatory scheme regarding a particular product or industry, while allowing state damages actions arising from those regulated activities to go forward. *See Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) (preemption of state positive law, but not state common law "does not produce anomalous results. It would have been perfectly rational for Congress not to pre-empt common-law claims, which — unlike most administrative and legislative regulations—necessarily perform an important remedial role in compensating accident victims.") (citing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)); *Cipollone*, 505 U.S. at 518 ("there is no general, inherent conflict between [express] federal preemption of state [regulatory] warning requirements and the continued vitality of state common-law damages actions"); *Goodyear Atomic*, 486 U.S. at 185-86 ("The effects of direct regulation ... are significantly more intrusive than the incidental regulatory effects of such an award provision. ...Congress may reasonably determine that incidental regulatory pressure is acceptable, whereas direct regulatory authority is not."); *Silkwood*, 464 U.S. at 256 (despite federal preemption of state regulatory authority, state-law punitive damages awards not preempted even though "regulatory in the sense that a nuclear plant will be threatened with damages liability if it does not conform to state standards").

State damages actions serve to highlight defects in the EPA-approved labels. It is hard to imagine state damage actions leading to conflicting labels because the manufacturer retains the ability to draft the label to meet all its obligations. Instead, state damage actions create an incentive for registrants to submit more complete and informative labels to EPA for approval and to ensure that pesticides are not misbranded by virtue of inadequate warnings of health and environmental effects. Compliance with any such state common law obligation to provide warnings and precautionary information on the pesticide label promotes the overall FIFRA goal of

protecting the public from the adverse effects of pesticide use, without creating any conflict between a manufacturer's FIFRA obligations and compliance with that duty.

For example, *Rumsey v. Freeway Manor Minimax*, 423 S.W.2d 387 (Tex. App. 1968), involved a three-year-old boy's ingestion of a roach poison, which led to his death. The court held that the evidence could support a finding of negligence because the label identified an antidote when, in fact, there was no antidote for the insecticide. Such a finding would likely spur the registrant to modify the label to disclose the lack of an antidote and the full risks of ingestion of the poison.

Likewise, in 1999, crawfish farmers brought a class action alleging fraudulent and negligent misrepresentation for marketing the insecticide fipronil for use on rice crops in Louisiana. Fipronil is highly toxic to aquatic invertebrates, including crawfish, and in Louisiana, rice and crawfish farms occur in close proximity, often in the same pond. The farmers used fipronil on rice seed to combat the rice water weevil, but suffered significant declines in crawfish production in adjacent areas. The class action resulted in a $45 million settlement in March 2004. A few months later, the registrant asked EPA to cancel registration of its pesticide products containing fipronil for use on rice. 69 Fed. Reg. 39,927 (July 1, 2004).

Similarly, in 1977, EPA found that the fungicide benomyl caused unreasonable adverse effects based on, among other things, evidence of birth defects, including rats born without eyes or with very small eyes after in utero exposure to benomyl. 42 Fed. Reg. 61,788 (Dec. 6, 1977). Initially, EPA proposed to cancel benomyl registrations unless the labeling warned that "benomyl causes birth defects and reduced sperm production in laboratory animals. Exposures to benomyl during pregnancy should be avoided." 44 Fed. Reg. 51,166, 51,169 (Aug. 30, 1979). In its final determination, EPA backtracked and required that the label state only: "Harmful if inhaled. Wear a cloth or disposable paper dust mask during handling and mixing." 47 Fed. Reg. 46,747, 46,750 (Oct. 20, 1982).

Over the years since, dozens of children in rural areas have been born with no or tiny eyes after their mothers were exposed to benomyl during pregnancy. A jury awarded $4 million to the family of one such child whose mother was exposed by applications at a nearby farm. *Castillo v. E.I. DuPont de Nemours, Co.*, 854 So.2d 1264 (Fla. 2003).

Although EPA initially addressed the potential for birth defects from benomyl through label warnings, Dupont ultimately requested cancellation of all of its registrations and ceased production of benomyl in 2001, 67 Fed. Reg. 1919 (Jan. 15, 2002), and EPA thereafter issued a notice phasing out remaining uses of benomyl. 67 Fed. Reg. 46,900 (July 17, 2002). Under FIFRA, the states had the authority to ban use of benomyl on the ground that it could not be used, even with extensive warnings, without causing unreasonable adverse effects, such as birth defects. Thus, the states plainly had the lesser authority to provide damages awards on the ground that benomyl was misbranded.

C. State Damages Actions Complement and Fill Gaps in the FIFRA Regulatory Scheme.

Many courts holding that FIFRA preempts state damages actions have assumed that EPA has made a finding that predetermines the outcome of the state law question that would be presented to a jury in such a case. While FIFRA's unreasonable adverse effects standard resembles the legal duty underlying some state law duties, EPA does not even purport to guard against unreasonable adverse effects in certain contexts.

This case concerns such a gap in that EPA neither reviews nor makes finding concerning the efficacy of most pesticides. A 1978 FIFRA amendment expressly authorized EPA to waive data requirements pertaining to a product's efficacy and to register such pesticides without determining that the composition warrants proposed claims of efficacy. 7 U.S.C. § 136a(c)(5). Pursuant to this authority, EPA waived review of

efficacy claims for most pesticides. 40 C.F.R. § 158.640(b). Accordingly, EPA registers most pesticides without determining whether their composition warrants the efficacy claims made by the registrant, such as the claims made by respondent that led to damage to petitioners' crops.

Efficacy claims are not alone. EPA never passes on the unreasonable adverse effects of many pesticides either because the registrant has concealed information needed to make such an assessment or because FIFRA authorizes the pesticide use without such a finding. Even where EPA makes such a determination, it never purports to require notice to members of the public who unwittingly may find themselves exposed to pesticides wafting away from their targets and into unwelcome locations.

1. FIFRA Allows Temporary Authorizations of Pesticide Uses that Lack FIFRA Registrations.

Under FIFRA, some pesticide uses may be authorized even though the particular pesticide use has not passed muster under FIFRA's "unreasonable adverse effects" standard. First, states may register federally registered pesticides for additional uses that are not permitted on the pesticide label. 7 U.S.C. § 136v(c). Such state registrations, known as special local need registrations, become effective upon state approval and remain effective until rescinded by the state or by EPA. As part of the state approval, the state prescribes directions for use, including the information that must be provided to users or the public. No EPA approval is required for a state local needs permit to become effective.

Second, FIFRA authorizes EPA to exempt state or federal agencies from FIFRA requirements in emergency conditions. *Id.* § 136p. Under this authority, EPA grants temporary exemptions from EPA registration requirements for particular uses of pesticides that are not permitted under FIFRA registrations. Typically, a state requests an emergency

exemption and submits to EPA proposed conditions for the pesticide. Upon obtaining EPA approval, the state then authorizes and imposes the agreed-upon conditions on the pesticide use. While EPA makes an unreasonable adverse effects determination for an emergency exemption, it does so based on an expedited review of far more limited information than required for a registration and focusing on the impacts of the use for only one year, even though emergency exemptions may be sought for successive years. 40 C.F.R. § 166.25(b).

For example, in *Macias v. State of California*, 897 P.2d 530 (Cal. 1995), a boy who became blind after being sprayed by malathion as part of California's medfly eradication program brought a failure-to-warn claim. The California Department of Food and Agriculture had issued a special local need registration and obtained an emergency exemption to allow use of malathion for an unregistered use. The case challenged the manufacturer's and the state's failure to warn the public of the health hazards posed by the aerial spraying. While the California Supreme Court did not allow the boy to challenge the manufacturer's failure to provide warnings in connection with a state-administered emergency program, it did not find the claim against the state to be barred. *Id.* at 538-40. Nothing in FIFRA precluded the state from requiring public notification of the health risks of the aerial spraying, particularly since the state established the parameters of the spraying program embodied in its special local needs permit and medfly eradication program.

2. EPA-Approved Labels Are Not Intended To Provide Warnings To The Public, As Opposed to the Purchaser or User, About the Risks Posed by Pesticides.

Although some failure to warn claims might spur the registrant to strengthen the warnings on the EPA-approved label, others such claims seek warnings that cannot be provided

through the product label. FIFRA labels are attached to the pesticide product as it moves through the streams of commerce. Although they may convey warnings and directions for use to the direct purchaser or user, labels do not reach members of the public who may be unwittingly exposed to pesticides.

For example, spray drift is a key mechanism through which pesticides migrate away from their target and cause harm to the public. States receive about 2500 complaints of drift each year, and many more go unreported. http://www.epa.gov/opppmsd1/PR_Notices/prdraft-spraydrift801.htm, at 3. Many pesticide labels include a general direction, such as "Do not allow drift," but EPA has recently proposed to require clearer and more specific directions for preventing spray drift, which establish no-spray buffer zones, maximum wind speeds, and aerial equipment limitations. 66 Fed. Reg. 44,141 (Aug. 22, 2001); http://www.epa.gov/opppmsd1/PR_Notices/prdraft-spraydrift801.htm.

Ordinarily, the pesticide purchaser or applicator will see the pesticide label. Pesticide drift, however, can reach neighboring homes and farms, schools in the vicinity, and the public at large. There is a growing body of evidence, for example, that the children of farmworkers are exposed to pesticide residues in their homes both as a result of drift and residues on their parents' clothing. *See, e.g.*, Thompson, et al., "Pesticide Take-Home Pathway Among Children of Agricultural Workers," 45 J. Occ. Envt'l Med. 42 (2003) (take-home exposure and drift present increased risk for farmworker children); Fenske, et al., "Strategies for Assessing Children's Organophosphorous Pesticide Exposures in Agricultural Communities," 10 J. Expos. Anal. Envt'l Epid. 662 (2000) (levels of pesticides in farmworker children from drift and take home exposures exceed EPA safe levels in substantial fraction of farmworker children); Natural Resources Defense Council, *Trouble on the Farm: Growing up with Pesticides in Agricultural Communities*, Oct. 1998 (available at

http://www.nrdc.org/health/kids/farm/farminx.asp). Many lawsuits have been brought by such innocent bystanders who did not choose to use the pesticide but were nonetheless exposed and harmed, *see, e.g., Castillo v. E.I. DuPont de Nemours*, 854 So.2d 1264 (Fla. 2003), including cases involving school children mistakenly sprayed by pesticides. *See, e.g., Henderson v. Dept. of Agriculture*, 875 P.2d 487, 488 (Or. App. 1994); DePalma, "When Pest Killers Make Mistakes," *New York Times*, at B1, Sept. 1, 2004. In none of these instances would a pesticide label warning have reached the injured party to allow them to avoid being in harm's way, and, indeed, EPA does not regulate the relationship between pesticide registrants and members of the general public, who may be unwittingly exposed to pesticides applied in public places or that drift away from their intended site.

FIFRA's preemption provision is limited to "labeling or packaging," which FIFRA defines as the material intended to accompany the pesticide through the streams of commerce. Pesticide labeling does not encompass all communications made by a manufacturer in connection with the sale or marketing of a pesticide product. FIFRA, therefore, leaves the registrants other means to convey information to pesticide purchasers and users, none of which needs to be submitted to EPA as part of the approval process. *See, e.g.*, 40 C.F.R. § 152.168(b).

The local ordinance at issue in *Wisconsin Public Intervenor* required the posting of placards on sprayed areas notifying the public of the pesticide application and any applicable re-entry periods. 501 U.S. at 603. This Court never suggested that such a public notice requirement might be barred by FIFRA's express preemption provision.

In addition, two federal courts of appeals have explicitly distinguished between preempted pesticide labels, which go to the purchaser of the pesticide, and other permissible communications designed to warn the general public of risks of pesticide uses. In *Chemical Mfrs. Specialties Ass'n v. Allenby*,

958 F.2d 941, 946 (9th Cir.), *cert. denied*, 506 U.S. 825 (1992), the Ninth Circuit held that FIFRA does not preempt point-of-sale warnings on products containing carcinogens and reproductive toxins mandated by California's Proposition 65 because:

> FIFRA's definition of labeling cannot encompass every type of written material accompanying the pesticide at any time. If this were true, then price stickers affixed to shelves, sheets indicating that a product is on sale, and even the logo on the exterminator's hat would all constitute impermissible labeling.

Although there was no question that Proposition 65, as an affirmative enactment, is a state regulation within the meaning of FIFRA's preemption provision, the court held that Proposition 65 warnings do not constitute labeling requirements under FIFRA. *Id.* at 946-47.

Similarly, in *New York State Pesticide Coalition v. Jorling*, 874 F.2d 115 (2d Cir. 1989), the Second Circuit refused to construe the term "labeling" in § 136v(b) to include warnings given to customers who contract for pesticide services or public notification of pesticide applications. Because a construction of "labeling" to include anything that could be said to "accompany" a pesticide would literally include "the logo on the applicator's hat and the license plate on the vehicle in which the pesticide is transported," the court limited that definition to material attached to the immediate container or otherwise expected to remain with the pesticide during the period of use. *Id.* at 119-20 (quoting letter from EPA's general counsel).

These decisions effectuate Congress' purpose to have uniform labels on pesticides sold in interstate commerce, *see Allenby*, 958 F.2d at 944, without embracing broad preemption of a whole range of state regulation that was never contemplated by Congress. Both *Allenby* and *Jorling* distinguished between FIFRA labels, which are designed to reach the purchaser and often the end user, from warnings that

are directed to the general public or others who may encounter pesticides during or after their application.[3] Given that nothing in FIFRA requires or prohibits such public or innocent bystander warnings, and FIFRA's preemption is limited to "labeling," states remain free to require such public notice as a condition of pesticide sale or use. Similarly, FIFRA cannot be read to preempt state failure-to-warn claims brought by such innocent bystanders.

Exercising their authority to regulate pesticide use, several states have adopted protective safeguards constraining pesticide applications around schools. Some states have required notification of students, teachers, and staff before pesticides are applied on school grounds. *See, e.g.*, Wyo. Stat. § 35-7-350; 302 Ky. Admin. Regs. 29:050, § 12; N.H. Code Admin. R. Pes 506.04. Other states have established a buffer zone around schools and other public buildings where aerial pesticide applications are prohibited. N.J. Admin. Code § 7:30-10.6(q); La. Admin. Code tit. 7, § 149(B).

Such state regulation fills gaps in federal regulation of pesticide sale and use through EPA registration of pesticides. FIFRA expressly authorizes such state supplementation through affirmative state regulation. State damages actions similarly fill gaps left by FIFRA, albeit indirectly. Because the registrant retains full authority and legal duties under FIFRA to ensure that its registrations and pesticide labels prevent unreasonable adverse health and environmental effects, state damages action promote the FIFRA scheme.

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[3] *Allenby* and *Jorling* involved both the provision of information to purchasers and public notice. The point-of-sale warnings in *Allenby* and the customer disclosures in *Jorling* would reach the purchaser of the pesticide products or services, while point-of-sale warnings and public notices on places where pesticides had been applied would notify the general public. The courts of appeals did not distinguish between the recipients in holding that FIFRA does not preempt such off-label warnings.

CONCLUSION

The decision below should be reversed.

Respectfully submitted,

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September 13, 2004

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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Office of Prevention, Pesticides and Toxic Substances

Jan 7 1994

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Dear Ms. Goldman:

Thank you for your letter of November 5 urging the Environmental Protection Agency (EPA) to support the position that the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) does not preempt state tort actions. There appear to be reasonable legal arguments for the position that FIFRA does not preempt such lawsuits. After reviewing the legal framework and the policy considerations, I conclude that EPA would clearly prefer the legal interpretation that FIFRA does not preempt state tort actions.

As you know, under FIFRA, EPA is responsible for registering pesticides on the basis of scientific data adequate to demonstrate that their use in accordance with label directions will not result in unreasonable adverse effects on people or the environment. The Agency carefully reviews product labels to ensure that they provide users with adequate information on the proper use of a pesticide. There are currently many pesticide products on the market that have not been reviewed according to modern standards. We are

currently directing much of our resources toward the reregistration program for reviewing large amounts of data on these older pesticides. This effort, however, is clearly costly and time consuming.

With limited government resources available to regulate a growing number of pesticide products, we believe that tort litigation can be an effective tool and ally to the regulatory process. If tort actions are not preempted by FIFRA, manufacturers' concern about possible tort liability may well lead then to take additional steps to provide users with information about their products. Such information could, in turn, enable users to choose and use pesticides in ways that are safer for themselves, others, and the environment.

Accordingly, the Agency will consider opportunities to participate in ongoing litigation where FIFRA tort preemption is an issue. I hope this information is useful. Please let me know if I may be of further assistance.

Sincerely yours,

Lynn R. Goldman
Assistant Administrator

(19)

No. 03-388

In the Supreme Court of the United States

DENNIS BATES, *ET AL.*,

Petitioners,

v.

DOW AGROSCIENCES LLC,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF FOR THE PRODUCT LIABILITY ADVISORY COUNCIL, INC., AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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QUESTION PRESENTED

Whether state law claims for crop injury are preempted by the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-137?

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BRIEF FOR THE PRODUCT LIABILITY ADVISORY COUNCIL, INC., AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

INTEREST OF THE *AMICUS CURIAE*[1]

The Product Liability Advisory Council, Inc. ("PLAC") is a non-profit association with 132 corporate members representing a broad cross-section of American and international product manufacturers. These companies seek to contribute to the improvement and reform of the law in the United States and elsewhere, with emphasis on the law governing the liability of manufacturers of products. PLAC's perspective is derived from the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. Since 1983, PLAC has submitted hundreds of briefs as *amicus curiae* in state and federal courts, including this Court, presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product liability. A list of PLAC's corporate members is reproduced in Appendix A.

Because many of PLAC's members manufacture products that are subject to preemptive federal requirements, they have a vital interest in the development of the law of preemption. PLAC has filed briefs in many of this Court's cases involving federal preemption, including *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Geier* v. *American Honda Motor Co.*, 529 U.S. 861 (2000); *Norfolk S.*

[1] The parties have consented to the filing of this brief; the written consents have been filed with the Clerk. This brief was not authored in whole or in part by counsel for a party, and no person or entity other than the *amicus curiae*, its members, and its counsel made a monetary contribution to the preparation and submission of this brief.

Ry. v. *Shanklin*, 529 U.S. 344 (2000); *United States* v. *Locke*, 529 U.S. 89 (2000); and *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996). Most recently, PLAC filed a brief supporting the petitioner in *BASF Corp.* v. *Peterson*, No. 04-81 (petition for cert. filed July 16, 2004), another case involving federal preemption under FIFRA. The petition in *Peterson* remains pending before this Court.

Because PLAC's members sell their products in every state in the nation, they understand the difficulty and costliness of attempting to comply with differing state law standards for product labeling. A single set of federal labeling standards is vastly superior as a matter of both common sense and public policy to a system in which label content is governed by the laws of 50 states. The advantages of a federally mandated labeling scheme are particularly pronounced when compared with state labeling "standards" established in litigation by lay juries applying broad tort principles.

When Congress enacted FIFRA, it wisely decided to establish nationally uniform pesticide labeling standards administered by an expert federal agency. The benefits of that rational, predictable, and consistent labeling system will be substantially eroded if judges and juries evaluating state law claims can second-guess federal law regarding the adequacy of labeling. PLAC believes that when Congress creates comprehensive, federally administered rules governing the labels of products that it regulates, allowing actions that challenge those labels under state law deprives PLAC members of the benefits — including predictability and uniformity — that Congress intended. Accordingly, PLAC has a strong interest in urging the Court to affirm the decision below.

STATEMENT

In the decision below, the Fifth Circuit correctly concluded that FIFRA expressly preempts state law claims, including claims arising from damage to crops, that rest on contentions that a pesticide's labeling is inadequate. In

PLAC's view, well-established principles of implied conflict preemption dictate the same conclusion.

1. *Federal Regulation of Pesticide Labeling.* FIFRA is a "comprehensive regulatory statute" (*Ruckelshaus* v. *Monsanto Co.*, 467 U.S. 986, 991 (1984)) that "creates a comprehensive regulatory scheme for pesticide and herbicide labeling." *Andrus* v. *AgrEvo USA Co.*, 178 F.3d 395, 398 (5th Cir. 1999); see also *Wisconsin Pub. Intervenor* v. *Mortier*, 501 U.S. 597, 601 (1991).[2] FIFRA grants EPA "exclusive supervision" of pesticide labeling. *New York State Pesticide Coalition, Inc.* v. *Jorling*, 874 F.2d 115, 118 (2d Cir. 1989). In a provision entitled "Uniformity," the statute expressly prohibits states from imposing "*any* requirements for labeling or packaging in addition to or different from those required" by EPA. 7 U.S.C. § 136v(b) (emphasis added). Congress intended this provision "to completely preempt State authority in regard to labeling." H.R. Rep. No. 92-511, at 16 (1971). See also *Arkansas-Platte & Gulf P'ship* v. *Van Waters & Rogers, Inc.*, 959 F.2d 158, 160 (10th Cir. 1992) ("*Arkansas-Platte I*") ("A plain reading of the statute indicates [a] * * * specific intent to occupy the field in labeling and packaging"), cert. granted and judgment vacated by *Arkansas-Platte & Gulf P'ship* v. *Dow Chem. Co.*, 506 U.S. 910 (1992).

EPA's authority over pesticide labeling is implemented primarily through the registration process. No pesticide may be sold in the United States unless it has first been registered with EPA. 7 U.S.C § 136a(a). To obtain registration, a pesticide manufacturer must submit to EPA "a complete copy of the labeling" of the pesticide. 7 U.S.C. § 136a(c)(1).[3] See

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[2] Herbicides fall within FIFRA's definition of "pesticide." See 7 U.S.C. § 136(u).

[3] "Labeling" means "all labels and all other written, printed, or graphic matter * * * accompanying the pesticide * * * at any time;

7 U.S.C. § 136a(c)(9). EPA will not register a pesticide unless it determines that its labeling "compl[ies] with the requirements of [FIFRA]." 7 U.S.C. § 136a(c)(5); see also 40 C.F.R. § 152.112(f)). Once approved, the labeling cannot be altered without EPA's permission. See 7 U.S.C. §§ 136j(a)(2)(A), 136(a)(f)(1); 40 C.F.R. § 152.44(a). An EPA regulation affirmatively provides that "[a] registrant may distribute or sell a registered product with the composition, packaging, and labeling currently approved by the Agency." 40 C.F.R. § 152.130(a).

In considering an application for pesticide registration, EPA has the authority to examine whether the pesticide's "composition is such as to warrant the proposed claims for it." 7 U.S.C. § 136a(c)(5). To address a backlog of registration applications, Congress amended FIFRA in 1978 to provide that EPA "*may* register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy" (7 U.S.C. § 136a(c)(5) (emphasis added)) and "*may* waive" requirements for submission of data pertaining to efficacy. *Id.* (emphasis added). EPA has by regulation "waived all requirements to submit efficacy data" in most cases, but requires each registrant to "ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices." 40 C.F.R. § 158.640(b)(1). The agency further "reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration." *Id.* EPA has stated that such a request "may be made for any product for which a pattern of inadequate performance has been reported." 44 Fed. Reg. 27,932, 27,939 (May 11, 1979).

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or * * * to which reference is made on the label or in literature accompanying the pesticide." 7 U.S.C. § 136(p)(2).

EPA has promulgated detailed labeling regulations, which "govern what must (and what cannot) appear on the label." EPA Label Review Manual 1-11 (3d ed. Aug. 2003), *available at* http://www.epa.gov/oppfead1/labeling/lrm/labelreviewmanual.pdf; see also 40 C.F.R. pt. 156 (Labeling Requirements for Pesticides and Devices). The regulations address both the design and content of pesticide labeling. 40 C.F.R. § 156.10. Among other things, they impose requirements for the "Directions for Use," a detailed set of instructions and warnings that *must* appear on the labeling. *Id.* § 156.10(a)(1)(viii). The directions "must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment" (*id.* § 156.10(i)(1)(i)) — including harm to crops.[4]

Although these labeling regulations appear comprehensive, they nonetheless understate EPA's broad and deep involvement in pesticide labeling.

> Because of the variety of pesticide products, purposes and uses, it is impossible for EPA to describe in regulatory form the majority of the individual labeling decisions that are required under the licensing scheme of FIFRA. EPA's labeling regulations in part 156 are of necessity general, serving as a framework for individual decisions and allowing flexibility for both the Agency and applicants to tailor actual labeling to the extent practicable to a particular product and its uses.

66 Fed. Reg. 64,759, 64,761 (Dec. 14, 2001).

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[4] "The term 'environment' includes water, air, land, and *all plants* and man and other animals living therein, and the interrelationships which exist among these." 7 U.S.C. § 136(j) (emphasis added).

Demonstrating the centrality of the label to the federal regulatory regime, a pesticide's labeling determines how it may lawfully be used. It is a violation of FIFRA, punishable by civil and criminal penalties, "to use any pesticide in a manner inconsistent with its labeling." 7 U.S.C. § 136j(a)(2)(G). A statement explaining this limitation must appear on every pesticide label. 40 C.F.R. § 156.10(i)(2)(ii).

EPA's supervision of pesticide labeling continues after a product is granted registration. FIFRA places registrants under an ongoing obligation to report to EPA "additional factual information regarding unreasonable adverse effects on the environment" of the registered pesticide. 7 U.S.C. § 136d(a)(2). The agency regulations implementing this provision require registrants to report instances of harm to crops, including specifically "phytotoxicity to the treated crop," unless "the label provides an adequate notice of such a risk." 40 C.F.R. §§ 159.184(a)(1)-(3), (b)(3)-(4). When it receives information about such unanticipated risks or other problems, EPA may cancel or suspend the pesticide's registration under 7 U.S.C. § 136d(b) or (c). It may also stop short of cancellation or suspension, instead engaging in "closer examination" of a pesticide, making a "request for additional information," or requiring "modifications to the terms and conditions of registration * * * necessitated by the balancing of the risks and benefits associated with a particular pesticide." 62 Fed. Reg. 49,370, 49,372 (Sept. 19, 1997). Such post-registration modifications of the terms and conditions of registration would be likely to include imposition of additional or different labeling requirements, such as "requiring different warning statements, application methods, or the use of personal protective equipment." *Id.* at 49,382.

EPA also may take action under FIFRA if it determines that a pesticide is "misbranded." 7 U.S.C. § 136j(a)(1)(E). A registered pesticide is considered "misbranded" if its labeling contains "any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular." *Id.* § 136(q)(1)(A). A pesticide is also "misbranded" if

> (F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 3(d) of [FIFRA], are adequate to protect health and the environment; [or]
>
> (G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 3(d) of [FIFRA], is adequate to protect health and the environment.

7 U.S.C. § 136(q)(1)(A). A "false or misleading statement concerning the effectiveness of the product as a pesticide" constitutes misbranding as well. 40 C.F.R. § 156.10(a)(5)(ii).

A misbranded product is subject to stop-sale orders and seizure, 7 U.S.C. § 136j, and persons found distributing or selling a misbranded product are subject to civil and/or criminal penalties, *id.* § 136l. EPA has stated that it "wishes to retain the flexibility to choose the appropriate response to evidence of incorrect labeling," based in part on its "day-to-day dealing with individual registrants." 47 Fed. Reg. 40,659, 40,663 (Sept. 15, 1982). "Where a good-faith effort has been made, the registrant should not be penalized unless the magnitude of the error creates serious label discrepancies or could be hazardous if followed by the user." *Id.*

2. *Proceedings Below.* Respondent Dow AgroSciences LLC ("Dow") manufactured and sold its herbicide Strongarm under labeling approved by EPA. Petitioners applied Strongarm to their peanut crops during the 2000 growing season. Petitioners claim that Strongarm "stunted the growth of peanut plants, caused yellowing, inhibited peanuts from lapping or properly developing foliage, delayed maturity, reduced

total peanut production, and increased the expense of harvesting future peanut crops." Pet. App. 2a. According to petitioners, they were unaware that Strongarm "would not be readily absorbed and would retard or injure the roots of the non-target peanut plants" when soil pH levels reached 7.0 or greater. Pet. Br. 9. With EPA's approval, Dow later added to the Strongarm label an instruction that the herbicide should not be applied to soils having a pH of 7.2 or greater. *Id.* at 11.

After petitioners threatened to sue Dow under state law, Dow initiated a federal action seeking a declaration that the farmers' claims were preempted by FIFRA. Pet. App. at 3a. Petitioners filed counterclaims alleging breach of warranty, fraud, defective design, negligence, and violation of the Texas Deceptive Trade Practices Act. *Id.* The district court granted summary judgment to Dow, ruling that FIFRA expressly preempted petitioners' claims because they effectively "challenge[d] the Strongarm label." *Id.* at 25a.

The Fifth Circuit affirmed. Carefully reviewing petitioners' claims, the court of appeals concluded that they all rested on a contention that the Strongarm label was inadequate. It stated: "One cannot escape the heart of the farmers' grievance: Strongarm is dangerous to peanut crops in soil with a pH level over 7.0, and that was not disclosed to them." *Id.* at 18a. Because "a judgment against Dow would induce it to alter its product label" to avoid future liability (*id.* at 15a), the court of appeals held that FIFRA expressly preempted petitioners' claims.

The court of appeals did not closely examine petitioners' contention "[t]hat the EPA had not elected to impose labeling requirements concerning product efficacy." *Id.* at 14a-15a. Observing that "FIFRA's express preemption clause is self-executing," the court of appeals rejected petitioners' assertion that EPA's regulations "define the domain expressly preempted by FIFRA" *Id.* at 14a, 15a (quoting *American Cyanamid Co.* v. *Geye*, 79 S.W.3d 21, 23 (Tex. 2002), cert.

denied, 539 U.S. 969 (2003)). Because it was persuaded that FIFRA expressly preempted petitioners' claims, the court below did not reach Dow's argument that the claims also were foreclosed by implied preemption principles.

SUMMARY OF ARGUMENT

Petitioners argue at length that FIFRA does not expressly preempt their claims because state law damages actions are not "requirements" within the meaning of Section 136v(b). See Pet. Br. 16-28. Even if petitioners' textual argument is correct, it does not follow that their claims may proceed. As this Court has made clear, the presence of an express preemption provision does not preclude the application of ordinary principles of implied conflict preemption. In this case, those principles operate decisively to preempt petitioners' claims, because their challenge to the adequacy of Dow's pesticide labeling undermines the congressional purposes underlying FIFRA.

When it enacted FIFRA, Congress intended to create a nationally uniform pesticide labeling regime under the exclusive direction and control of EPA. EPA has fully exercised that authority by promulgating comprehensive and detailed labeling regulations and reviewing all labeling before registering a pesticide. Both national uniformity and EPA's authority would be severely compromised if manufacturers were subject to damages liability because their labeling failed to satisfy state law tort standards. The need to anticipate and comply with the tort regimes of 50 states would adversely affect the quality of pesticide labels, hamper the interstate distribution of pesticides, impose unacceptable burdens on the federal registration process, and create untenable conflicts between federal and state law.

The amendment of FIFRA to authorize EPA's waiver of product efficacy data submission before registration does not cast doubt on the conclusion that FIFRA forecloses state law actions asserting damage to crops. Contrary to petitioners'

contentions, EPA continues to monitor product efficacy and to prohibit false or misleading efficacy claims on product labeling. After enacting the waiver authorization, moreover, Congress re-affirmed its commitment to federal control over labeling by re-enacting Section 136v(b) with its new subheading, "Uniformity." Because petitioners' claims boil down to the contention that Dow omitted an important instruction from its labeling, their action conflicts with the goal of uniformity and is impliedly preempted.

ARGUMENT

I. FIFRA'S EXPRESS PREEMPTION CLAUSE DOES NOT PRECLUDE A FINDING THAT PETITIONERS' STATE LAW CLAIMS ARE IMPLIEDLY PREEMPTED

By operation of the Supremacy Clause, U.S. Const. art. VI, cl. 2, state laws that "interfere with, or are contrary to" federal law (*Hillsborough County, Fla.* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 712 (1985) (internal quotation marks omitted)) are "without effect." *Maryland* v. *Louisiana*, 451 U.S. 725, 746 (1981). Federal law will not be deemed to override state law unless that is "the clear and manifest purpose of Congress." *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Preemption "is compelled," however, "whether Congress's command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *First Fidelity Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982) (quoting *Jones* v. *Rath Packing Co.*, 430 U.S. 519, 525 (1977)).

State law is implicitly preempted when "a scheme of federal regulation is 'so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.'" *Mortier*, 501 U.S. at 605 (quoting *Rice*, 331 U.S. at 230). "Even where Congress has not completely displaced state regulation in a specific area, state law is nullified to the extent that it actually conflicts with federal law." *First Fidelity Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. at 153. Such a conflict exists when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 873 (2000) (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)). Conflict preemption applies "whether that 'obstacle' goes by the name of 'conflicting; contrary to; . . . repugnance; difference; irreconcilability; inconsistency; violation; curtailment; . . . interference,' or the like." *Id.* (quoting *Hines*, 312 U.S. at 67) (omissions in original).

"[N]either an express pre-emption provision nor a saving clause 'bar[s] the ordinary working of conflict pre-emption principles.'" *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) (quoting *Geier*, 529 U.S. at 869). See also *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 287 (1995) (dismissing as "without merit" the suggestion "that implied pre-emption cannot exist when Congress has chosen to include an express pre-emption clause in a statute"); *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 503 (1996) (after finding no express preemption under the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act, observing that common law claims might still "be preempted under conflict pre-emption analysis"); *Boggs* v. *Boggs*, 520 U.S. 833 (1997) (employing implied conflict preemption analysis to decide case under the Employee Retirement Income Security Act despite presence of an express preemption clause). Thus, express and implied preemption are not mutually exclusive: a federal statute may preempt state law either or both ways. See *Geier*, 529 U.S. 861, 869 (2000) (citing *Freightliner*, 514 U.S. at 280). Put another way, the conclusion that a statute's express preemption provision does *not* nullify a particular state law does not preclude a finding that the state law is impliedly preempted. *Id.*

Before this Court decided *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992), several federal courts of appeals had concluded that, given Congress's evident intent to create

a uniform scheme of pesticide labeling, FIFRA *impliedly* preempts state law damages actions that, if successful, would induce the manufacturer to change its label. See *Arkansas-Platte I*, 959 F.2d at 162; *Papas* v. *Upjohn Co.*, 926 F.2d 1019, 1020 (11th Cir. 1991) ("*Papas I*"), cert. granted and judgment vacated by *Pappas* v. *Zoecon Corp.*, 505 U.S. 1215 (1992). Petitions for certiorari were pending in both *Arkansas-Platte I* and *Papas I* when *Cipollone* was decided. The Court ruled in *Cipollone* that the Federal Cigarette Labeling and Advertising Act, which contains a provision having language similar to Section 136v(b) of FIFRA, *expressly* preempts certain state law damages actions. Thereafter, the Court granted, vacated, and remanded both *Arkansas-Platte I* and *Papas I* for further consideration in light of *Cipollone*. *Arkansas-Platte & Gulf P'ship* v. *Dow Chem. Co.*, 506 U.S. 910 (1992); *Papas* v. *Zoecon Corp.*, 505 U.S. 1215 (1992).

Considering those cases on remand, the Tenth and Eleventh Circuits held in light of *Cipollone* that Section 136v(b) of FIFRA *expressly* preempts state law damages actions, including failure-to-warn claims, that challenge pesticide labels. See *Arkansas-Platte & Gulf P'ship* v. *Van Waters & Rogers, Inc.*, 981 F.2d 1177, 1179 (10th Cir.) ("*Arkansas-Platte II*") ("We believe Congress circumscribed the area of labeling and packaging and preserved it only for federal law."), cert. denied, 510 U.S. 813 (1993); *Papas* v. *Upjohn Co.*, 985 F.2d 516, 518 (11th Cir.) ("*Papas II*") (holding that "the *Cipollone* opinion dictates, under an express preemption analysis, the same result we reached earlier under the implied preemption doctrine"), cert. denied, 510 U.S. 913 (1993). Since *Cipollone*, most courts considering whether FIFRA preempts state law damages claims — including the Fifth Circuit in the decision below — have analyzed the issue under express preemption principles. See, *e.g.*, *MacDonald* v. *Monsanto Co.*, 27 F.3d 1021, 1025 (5th Cir. 1994); *Taylor AG Indus.* v. *Pure-Gro*, 54 F.3d 555, 560 (9th Cir, 1995).[5]

Nevertheless, implied preemption remains a viable and important part of the analysis of whether FIFRA forecloses a state law claim. Even if a claim falls outside the express terms of Section 136v(b), a court nonetheless may find that it is implicitly preempted by FIFRA or its regulations. The Ninth Circuit, for example, recently relied on implied preemption in dismissing a state law claim raising allegations that the defendant lied to EPA to obtain approval of label directions that precluded its customers' use of the plaintiff's product. See *Nathan Kimmel, Inc.* v. *DowElanco*, 275 F.3d 1199, 1204 (9th Cir. 2002). The court stated that it was unnecessary "to determine the exact length of the preemptive shadow cast by the express language of § 136v * * * because ordinary conflict principles dictate that [plaintiff's] state law claim is *impliedly* preempted by FIFRA." *Id.* (emphasis in original).

If the Court is not persuaded that Section 136v(b) expressly preempts petitioners' claims — for example, if it accepts petitioners' argument that state law actions seeking damages for past harms do not impose "requirements" — it should examine whether the claims are impliedly preempted. See *Buckman*, 531 U.S. at 348 & n.2 (expressing no view as to whether the claims at issue were subject to express preemption in light of the Court's conclusion that such claims were impliedly preempted). As we discuss below, implied preemption provides a valid alternative ground for affirming the Fifth Circuit's decision. See *SEC* v. *Chenery Corp.*, 318 U.S. 80, 88 (1943) (describing "the settled rule that, in re-

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[5] Indeed, some courts of appeals construed *Cipollone* to preclude a finding of implied preemption under FIFRA. See, *e.g.*, *Taylor AG Indus.*, 54 F.3d at 560. This Court has since made clear that this is an incorrect reading of *Cipollone*. See *Freightliner*, 514 U.S. at 287.

viewing the decision of a lower court, it must be affirmed if the result is correct 'although the lower court relied upon a wrong ground or gave a wrong reason'" (quoting *Helvering* v. *Gowran*, 302 U.S. 238, 245 (1937))); see also *Schenck* v. *Pro-Choice Network*, 519 U.S. 357, 384 (1997) (same).

II. FIFRA IMPLIEDLY PREEMPTS STATE LAW CLAIMS, INCLUDING CLAIMS FOR CROP INJURY, ARISING FROM ALLEGED FLAWS IN PESTICIDE LABELING

Petitioners' state law claims conflict with Congress's objective to create a nationally uniform pesticide labeling regime under the exclusive supervision of EPA. Moreover, they are incompatible with the substantive statutory and regulatory provisions that further this goal. Accordingly, FIFRA and its regulations impliedly preempt petitioners' claims. Contrary to petitioners' argument (Pet. Br. 30-37), EPA's decision to discontinue the routine review of product efficacy data prior to registration — an action that had no direct impact on EPA's firm control over pesticide *labeling* — does not undercut that conclusion.

A. Congress Intended To Create A Uniform Pesticide Labeling Regime Under EPA's Exclusive Control

FIFRA's text, structure, and legislative history demonstrate that Congress intended to create a nationally uniform system of pesticide labeling administered exclusively by EPA. That purpose is expressed unmistakably in the text of Section 136v(b), including its title, which was added in 1988. See, *e.g.*, Act of Oct. 25, 1988, Pub. L. No. 100-532, 102 Stat. 2654 (adding subheading "Uniformity" to Section 136v(b)); S. Rep. No. 95-334, at 4 (1977) (characterizing EPA-approved product labeling as "the final authority" governing the application of a pesticide); *MacDonald*, 27 F.3d at 1024 (describing § 136v(b) as "an effort to preserve uniformity of laws concerning labeling"); *Arkansas-Platte I*, 959 F.2d at 162 (purpose of § 136v(b) is to "ensure uniform labeling standards"); *Papas I*, 926 F.2d at 1025 (stating that Congress has endorsed objective of obtaining nationwide uniformity in labeling).

That goal also is apparent in FIFRA's substantive provisions. The statute requires EPA to review the labeling of every pesticide marketed anywhere in the country (7 U.S.C. § 136a(c)(1)), establishes standards for that labeling (*id.* §§ 136a(c)(5), 136j(a)(1)(E)), and forbids pesticide use that is inconsistent with that labeling (*id.* § 136j(a)(2)(G)). These provisions reinforce Section 136v(b)'s message that state law has no role to play in determining the adequacy of pesticide labeling. It is inconceivable that Congress would have required EPA to review all pesticide labeling, instructed the agency what to consider in evaluating the labeling, and mandated that users follow the labeling, if it did not expect EPA to have the final say on the contents of the labeling.

Furthermore, "[f]ederal regulations have no less preemptive effect than federal statutes," and their force "does not depend on express congressional authorization to displace state law." *First Fidelity Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. at 153, 154 (1982). Acting well within its authority under FIFRA, EPA has asserted complete control over federal labeling by issuing comprehensive labeling requirements, reviewing every label, and providing that pesticides may be sold under their approved labeling. See 40 C.F.R. § 152.130(a). These regulations leave no room for contrary or additional state law requirements.

B. State Law Damages Actions That Challenge The Adequacy Of Pesticide Labels Would Undermine FIFRA's Goals

As this Court recently stated in *Geier*, a congressional policy of nationwide regulatory uniformity "favors preemption of state tort suits." 529 U.S. at 871. That is because

> the rules of law that judges and juries create or apply in such suits may themselves similarly create uncertainty and even conflict, say, when different juries in different States reach different decisions on similar facts.

Id. The Court's observation in *Geier* applies fully here: allowing state law damages actions would substantially erode the benefits of the nationally uniform pesticide labeling scheme created by FIFRA. See *Arkansas-Platte I*, 959 F.2d at 162 ("State court damage awards * * * would constitute ad hoc determinations of the adequacy of statutory labeling standards [which] would hinder the accomplishment of the full purpose of 136v(b), which is to ensure uniform labeling standards.").

Labeling-related claims such as those asserted by petitioners allow courts and juries "to sit, in effect, as super-EPA review boards," second-guessing the content of EPA-approved labeling. *Welchert* v. *American Cyanamid, Inc.*, 59 F.3d 69, 73 (8th Cir. 1995). If pesticide manufacturers were subject to liability for failure of their labels to satisfy state-imposed tort standards, they would have to wind through the variations of 50 states' tort-law systems, rather than federal law alone, when making labeling decisions. Such a radical change in the regulation of pesticide labeling would have predictably adverse consequences.

1. "As a practical matter, complying with the [agency's] detailed regulatory regime in the shadow of 50 States' tort regimes [would] dramatically increase the burdens facing potential [registrants] — burdens not contemplated by Congress in enacting" FIFRA. *Buckman*, 531 U.S. at 350. No pesticide may be marketed in the United States unless EPA first approves the label (7 U.S.C. § 136a(c)(5)), and proposed label changes must be pre-cleared (*id.* § 136a(f)(1)). If state law played a role in determining label content, the agency would be overwhelmed (and registrants burdened) with requests for approval of label changes and state-specific variations.

The flood of requests for approval of label changes would portend more serious problems, because the agency's judgments about what should be included on the label no longer would be authoritative. Although EPA might conclude that a particular warning or instruction was unnecessary or counterproductive, a manufacturer facing state law liability for lack of that warning or instruction would be hard-pressed to exclude it. There would be no effective way to mediate such clashes between EPA's expert views and the vagaries of state jury verdicts. The conflict would be made more acute by FIFRA's provision that no pesticide may be used "in a manner inconsistent with its labeling." 7 U.S.C. § 136j(a)(2)(G).

For example, a loss in state court litigation might impel a manufacturer to instruct against use of its pesticide in combination with another chemical. If included on the labeling, such an instruction would make a farmer's use of the combined products illegal under FIFRA. *Id.* EPA might deem the combination perfectly safe, however, and thus object to the proposed labeling change. The manufacturer then would face the unhappy choice of complying with EPA's directions or complying with state law — but could not do both. When conflicting state and federal requirements make simultaneous compliance impossible, the state law is preempted. See *Freightliner*, 514 U.S. at 287.

Petitioners contend that their claims reinforce rather than conflict with FIFRA's "misbranding prohibitions" because they "giv[e] a remedy to injured farmers for the pesticide manufacturer's failure to ensure that its label is accurate." Pet. Br. 37. But FIFRA expressly authorizes EPA, not lay juries, to determine whether pesticide labeling meets federal standards *and* to decide on the proper response to a violation. See, *e.g.*, 7 U.S.C. § 136g(c)(1) (authorizing EPA to deter-

mine "whether [pesticides] comply with the requirements" of FIFRA); *id.* § 136k(a) (authorizing EPA to forbid the sale or use of any pesticide if it has "reason to believe * * * that such pesticide * * * is in violation of any of the provisions of this subchapter"); § 136q(b)(1)-(6) (authorizing EPA to recall a pesticide); § 136d(b) (authorizing EPA to cancel the registration of a pesticide).[6] EPA is required to consider the impact of its response "on production and prices of agricultural commodities, retail food prices, and otherwise on the national economy." *Id.*

Even if the "standards imposed by federal law" (Pet. Br. 38) could be enforced by jurors evaluating *state law* causes of action, as petitioners implausibly suggest, such actions would undermine EPA's "flexibility to choose the appropriate response to evidence of incorrect labeling." 47 Fed. Reg. at 40,663. Accordingly, petitioners' argument that their claims impose requirements *consistent* with FIFRA does not allow them to avoid implied preemption.

2. In the absence of preemption, EPA might be forced to accede to requests for litigation-focused labeling changes to avoid having the manufacturer simply de-register the pesticide to avoid liability. Under that scenario, pesticide labeling would lose much of its value as a clear, consistent, and reliable mechanism for conveying to users the essential information about pesticides and their proper use. Users accustomed to standard labeling, with form and content approved by a single expert decision-maker, would face a Tower of Babel: pesticides would bear discordant and inscrutable warnings derived from litigation, or fear of litigation, under the differing laws of 50 different jurisdictions.

[6] In addition, FIFRA and its regulations provide for the imposition of administrative, civil, and criminal penalties for violations. See 7 U.S.C. § 136l(a) and (b); 40 C.F.R. pt. 22.

Under a state law driven labeling regime, manufacturers would use inconsistent language to describe the risks associated with their products. For example, a manufacturer headquartered in a state with stringent product liability laws might include very strongly worded warnings on its labeling, while a manufacturer located elsewhere, marketing a pesticide with the exact same risk profile, might include fewer warnings or none at all. Faced with such different warning currencies, users would have difficulty comparing the benefits and risks of using different products, making the market a less efficient mechanism for weeding out riskier pesticides.

Even worse, pesticide users would be forced to monitor and evaluate a constantly changing set of warnings, as the labels evolved over time in response to litigation and changing state standards. Although some labeling changes might be justified by new information, others might be prompted by arbitrary jury verdicts, unfavorable settlements, or the mere threat of litigation. Because pesticide users would have no way to distinguish serious warnings from frivolous ones, they might insufficiently heed important new cautions or overreact to purely protective disclaimers.

In the end, the warnings and instructions on pesticide labeling no longer would reflect the considered judgments of manufacturers and the learned agency that supervises them. Instead, label content would be imposed by lay judges and jurors, who might have sympathy for local farmers but lack any special understanding of pesticides or the broader national interests that now inform their regulation. The addition of disclaimers over time would lead to overcrowded labels and "warning fatigue," a danger that has been recognized by many courts, including this one. See, *e.g.*, *Morales* v. *TWA, Inc.*, 504 U.S. 374, 390 (1992) (agreeing with the FTC that "'[r]equiring too much information in advertisements can have the paradoxical effect of stifling the information that consumers receive'" (alteration in original)); *Witty* v. *Delta Air Lines, Inc.*, 366 F.3d 380, 385 (5th Cir. 2004)

("[W]arnings by their nature conflict, in the sense that the import of one warning is diluted by additional warnings that might be imposed under state law."); *Hood* v. *Ryobi Am. Corp.*, 181 F.3d 608, 611 (4th Cir. 1999) ("Well-meaning attempts to warn of every possible accident lead over time to voluminous yet impenetrable labels * * * ."). Users inevitably would lose confidence in the labels, and FIFRA's strong policy that the labeling should guide all pesticide use would be substantially undermined.

3. A tort-driven labeling system also would burden the interstate distribution of pesticides. Although some manufacturers might use monolithic labels designed to satisfy the tort regimes of *all* states at once — thus including on all labels the warnings and limitations mandated by the most restrictive states — others would sell their products bearing different labels in different states. Thus, they would have to carefully tailor the production and shipment of appropriately packaged pesticides to the anticipated demand in each state, with failure to do so leading to inefficient surpluses and shortages. The added complexity of the distribution chain might cause manufacturers to limit their product lines, stop serving niche markets, or pull out of less profitable or more litigious geographic markets entirely.

Manufacturers wishing to simplify their labels also might simply avoid certain states and certain crop markets. Farmers living in notoriously plaintiff-friendly states or growing low-acreage, high-value crops might discover that there were no pesticides available to meet their needs. This would damage farmers economically and create risk to the food supply.

4. Another case pending before the Court illustrates how label-based state law claims can clash with the federal regulatory regime under an overly narrow view of preemption. In *BASF Corp.* v. *Peterson*, No. 04-81 (petition for cert. filed

July 16, 2004),[7] a pesticide manufacturer was sued in Minnesota state court under New Jersey's consumer protection statute by a nationwide class of farmers. The farmers claimed that the defendant had acted unconscionably by omitting certain crops from the list of approved uses on its pesticide's labeling. That labeling decision was authorized by EPA's "subset labeling" regulation (40 C.F.R. § 152.130(b)), which states that manufacturers may omit federally registered uses from final product labeling. Nevertheless, the Minnesota Supreme Court upheld a $52 million judgment in favor of the plaintiffs.

If *Peterson* is allowed to stand, manufacturers will be reluctant to take advantage of the labeling flexibility provided by EPA's rule, lest they suffer liability under some state's consumer fraud laws. This will undermine EPA's sound policy reasons for adopting the rule. Such clashes between broadly worded state law causes of action and the federal labeling regime will multiply exponentially unless the Court strongly affirms that state law damages actions challenging pesticide labels are preempted by FIFRA.

C. Notwithstanding EPA's Partial Waiver Of Efficacy Data Submission Requirements, FIFRA Preempts Petitioners' Label-Based Claims

According to petitioners, FIFRA does not preempt *their* claims — or any other claims seeking compensation for crop damage — because "Congress has expressly permitted EPA to waive any evaluation of the efficacy of pesticides prior to registration." Pet. Br. 30. "Because FIFRA no longer imposes a duty on EPA to evaluate the efficacy of any federally registered pesticide" (*id.*), they contend, their action would not interfere with any labeling requirement imposed under

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[7] As noted in PLAC's statement of interest, PLAC filed an *amicus* brief supporting the petition in *Peterson*.

FIFRA.[8] As we discuss below, however, the limited waiver of efficacy data submission and review requirements casts no doubt on the conclusion that FIFRA impliedly preempts all label-based state law claims, including claims arising from damage to crops.

1. The waiver of efficacy data submission and review requirements did not create a regulatory vacuum needing to be filled by state law. Contrary to petitioners' contention that product efficacy is now "unmonitored" (Pet. Br. 36), EPA remains actively involved in regulating product efficacy as it relates to labeling. See, *e.g.*, *Etcheverry* v. *Tri-Ag Serv., Inc.*, 993 P.2d 366, 375 (Cal. 2000) (rejecting "the argument that pesticide efficacy will go 'largely, or entirely, unregulated' if state law failure-to-warn claims are preempted"). "What has changed over time is the manner in which EPA is assured of product efficacy." 64 Fed. Reg. 50,672, 59,674 (Sept. 17, 1999).

Although the agency generally does not require manufacturers to submit efficacy data in the first instance, it *does* require manufacturers to *conduct* efficacy testing. EPA retains the power to request submission of the data and invokes this power whenever it has any reason for concern about the efficacy of a product. Moreover, EPA requires manufacturers to inform the agency of crop damage or other adverse events when the risk of those events has not been disclosed on the label. 40 C.F.R. §§ 159.184(a)(1)-(3), (b)(3)-(4). This activity — which brings to EPA's attention the same incidents that otherwise would give rise to private lawsuits — allows EPA to enforce its rule prohibiting the inclusion on pesticide labeling of "any false or misleading statement concerning the effectiveness of the product." 40 C.F.R. § 156.10(a)(5)(ii).

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[8] As used by petitioners, the term "efficacy" encompasses the pesticide's tendency to harm crops to which it is applied. *Id.* We adopt that same convention here.

Thus, the efficacy data waiver did not signal EPA's abandonment of the subject, but instead reflected the agency's judgment that its review of efficacy data prior to registration was unnecessary to its goals. Indeed, when it authorized EPA to waive review of efficacy data, Congress indicated that this authority should be invoked only when "the Administrator found that some other procedure for assuring the efficacy of pesticide products appeared to be sufficient." H.R. Rep. No. 95-663, at 27 (1977), *reprinted in* 1978 U.S.C.C.A.N., at 2000. When it ultimately did waive efficacy-data submission requirements, EPA pointed to "a general belief among persons in the pesticide industry, the U.S. Department of Agriculture and the agricultural community that the efficacy of agricultural pesticides can be effectively regulated by the marketplace (in conjunction with extension services and university research personnel)." 44 Fed. Reg. 27,932, 27,938 (May 11, 1979). In EPA's judgment, this belief proved correct: when EPA later "decided to retain the provisions concerning the waiver of efficacy data," it observed that it had "not been apprised of any increase in the number of ineffective pesticide products on the market." 48 Fed. Reg. 34,000, 34,003 (July 26, 1983).

Thus, EPA has repeatedly reaffirmed its initial judgment that its up-front review of manufacturers' efficacy data is superfluous. If preemption of state law claims nonetheless turned on EPA review of such data, however, registrants "would then have the incentive to submit a deluge of information that the [agency] neither wants nor needs, resulting in additional burdens on the [agency's] evaluation of an application" for registration. *Buckman*, 531 U.S. at 351. This would frustrate Congress's purposes in authorizing EPA to waive efficacy data submission requirements and EPA's purposes in exercising that authority.

2. When it amended FIFRA to permit *EPA* to waive its initial review of product efficacy data, Congress gave no hint that it intended to open the door to *state* regulation of pesti-

cide labeling on issues relating to product efficacy. To the contrary, after authorizing EPA to waive efficacy-data submission requirements, Congress reaffirmed its commitment to nationally uniform pesticide labels by reenacting Section 136v(b), making its intentions even more clear by adding the sub-heading "Uniformity." See Act of Oct. 25, 1988, Pub. L. No. 100-532, 102 Stat. 2654. EPA, for its part, did not eliminate its substantive requirements for pesticide labeling. The efficacy data waiver thus does not alter the implied preemption analysis.

3. Notwithstanding petitioners' effort to characterize their claims as falling within an area that EPA does not regulate, their action strikes at the core of EPA's congressionally mandated authority over pesticide labeling. As the court of appeals explained, petitioners' claims boil down to the contention that Strongarm's labeling failed to instruct them that it should not be used on high-pH soils. Pet. App. 18a. This is precisely the type of instruction that EPA's labeling standards squarely govern. See 40 C.F.R. § 156.10(a)(1)(viii). As discussed above, state law actions imposing such labeling standards conflict with the labeling regime that FIFRA creates. See pages 16-19, *supra*.

CONCLUSION

The decision below should be affirmed.

Respectfully submitted.

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NOVEMBER 2004

APPENDIX A

PLAC MEMBERS

3M
Allegiance Healthcare Corporation
Altec Industries
American Suzuki Motor Corporation
Andersen Corporation
Anheuser-Busch Companies
Ansell Healthcare, Inc.
Appleton Papers, Inc.
Aventis Pharmaceuticals Inc.
BASF Corporation
Baxter International, Inc.
Bayer Corporation
Beretta U.S.A Corp.
BIC Corporation
Biro Manufacturing Company Inc.
Black & Decker (U.S.) Inc.
BMW of North America, LLC
Bombardier Recreational Products
BP Amoco Corporation
Bridgestone/Firestone, Inc.
Briggs & Stratton Corporation
Bristol-Myers Squibb Company
Brown and Williamson Tobacco
Brown-Forman Corporation
Brunswick Corporation
C. R. Bard, Inc.
Caterpillar Inc.
Chevron Corporation
Compaq
Continental Tire North America, Inc.
Cooper Tire and Rubber Company
Coors Brewing Company
Crown Equipment Corporation

DaimlerChrysler Corporation
Dana Corporation
Deere & Company
E & J Gallo Winery
E. I. DuPont de Nemours and Company
Eaton Corporation
Eli Lilly and Company
Emerson Electric Co.
Engineered Controls International, Inc.
Estee Lauder Companies
ExxonMobil Corporation
FMC Corporation
Ford Motor Company
General Electric Company
General Motors Corporation
Georgia-Pacific Corporation
GlaxoSmithKline
Great Dane Limited Partnership
Guidant Corporation
Harley-Davidson Motor Company
Harsco Corporation, Gas & Fluid Control Group
Honda North America, Inc.
Hyundai Motor America
International Truck and Engine Corporation
Isuzu Motors America, Inc.
Johnson & Johnson
Johnson Controls, Inc.
Joy Global Inc.
Kawasaki Motors Corp., U.S.A.
Kia Motors America, Inc.
Kolcraft Enterprises, Inc.
Kraft Foods North America, Inc.
Lincoln Electric Holdings, Inc.
Mazda (North America), Inc.
Medtronic, Inc.
Mercedes-Benz of North America, Inc.

Michelin North America, Inc.
Miller Brewing Company
Mitsubishi Motors R & D of America, Inc.
Niro Inc.
Nissan North America, Inc.
Novartis Pharmaceuticals Corporation
Otis Elevator Company
PACCAR Inc
Panasonic
Pentair, Inc.
Pfizer Inc.
Pharmacia Corporation
Philip Morris Companies Inc.
Polaris Industries, Inc.
Porsche Cars North America, Inc.
Raytheon Aircraft Company
Rheem Manufacturing
RJ Reynolds Tobacco Company
Schindler Elevator Corporation
SCM Group USA Inc.
Sears, Roebuck and Co.
Shell Oil Company
Siemens Corporation
Smith & Nephew, Inc.
Snap-on Incorporated
Sofamor Danek, Medtronic Inc.
Solutia Inc.
Sturm, Ruger & Company, Inc.
Subaru of America, Inc.
Sunbeam Corporation
Synthes (U.S.A.)
Textron Inc.
The Boeing Company
The Dow Chemical Company
The Goodyear Tire & Rubber Company
The Heil Company

The Procter & Gamble Company
The Raymond Corporation
The Sherwin-Williams Company
The Toro Company
Thomas Built Buses, Inc.
Toshiba America Incorporated
Toyota Motor Sales, USA, Inc.
TRW Inc.
UST (U.S. Tobacco)
Volkswagen of America, Inc.
Volvo Cars of North America, Inc.
Vulcan Materials Company
Water Bonnet Manufacturing, Inc.
Whirlpool Corporation
Wilbur-Ellis Company
Wyeth
Yamaha Motor Corporation, U.S.A.
Zimmer, Inc.

(23)

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QUESTION PRESENTED

Which, if any, state law crop injury claims are preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§136-137 ("FIFRA")?

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U.S. DEPARTMENT OF AGRICULTURE STATISTICS 2

In the
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DENNIS BATES, *ET AL.*,
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INTEREST OF *AMICI CURIAE*

The state *amici curiae,* through their Attorneys General, respectfully submit this brief in support of Petitioners. The States have a vital interest in preserving their power to regulate traditional areas of state concern, such as the protection of consumers from unfair and deceptive practices. Nothing in the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§136-137, evinces an intent to eliminate the States' longstanding role in protecting their citizens and preventing deceptive conduct. Thus, the States have an interest in ensuring that FIFRA's preemption provisions are not construed more broadly than Congress intended.

The States have a further interest in defending state laws, and the court of appeals improperly held that FIFRA preempts the farmers' claims under the Texas Deceptive Trade Practices-Consumer Protection Act ("DTPA") and Texas common law.

The States also have a strong interest in matters affecting agricultural production and local farmers. The 2002 Census of Agriculture, prepared under the direction of the U.S. Department of Agriculture,[1] showed that the United States has approximately two million operating farms,[2] most of which are owned by individuals or families.[3] The gross farm income in the United States for 2002 was $228 billion,[4] and the estimated value of U.S. agricultural exports in 2004 is $61.5 billion.[5] The value of U. S. peanut production in 2003 was nearly $780 million,[6] and the value of Texas's peanut production in the same year was nearly $150

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1. *See* U.S. DEPARTMENT OF AGRICULTURE STATISTICS, NATIONAL AGRICULTURAL STATISTICS SERVICE, 2002 CENSUS OF AGRICULTURE, *at* http://www.nass.usda.gov/census/census02/volume1/us/CenV1US1.txt.

2. *Id.* (the census showed 2,128,982 farms).

3. *Id.* (the census showed 1,909,598 farms owned by individuals or families).

4. *See* U.S. DEPARTMENT OF AGRICULTURE STATISTICS, NATIONAL AGRICULTURAL STATISTICS SERVICE, *at* http://www.usda.gov/nass/pubs/agr04/04 ch9.pdf.

5. *See* U.S. DEPARTMENT OF AGRICULTURE STATISTICS, *at* http://www.usda.gov/Newsroom/0207.04.html.

6. *See* U.S. DEPARTMENT OF AGRICULTURE STATISTICS, NATIONAL AGRICULTURAL STATISTICS SERVICE, *at* http://www.usda.gov/nass/pubs/agr04/04 ch3.pdf.

million.[7] Given the size and importance to the States of the agriculture industry, they have an inherent interest in matters affecting their farmers and farm workers.

Because the efficacy of pesticides is vital to the livelihood of the States' citizen farmers and affects the quality of their agricultural commodities, the States have an ongoing interest in maintaining the broad program of federal-state cooperation in this area of pesticide regulation. Congress intended States to play a substantial role in regulating pesticides, and the court of appeals's decision weakens that role as a result of its erroneous conclusion that FIFRA preempts state law crop-injury claims.

Pursuant to express congressional authorization, the Environmental Protection Agency ("EPA") has waived review of pesticide label statements regarding the efficacy of pesticides when the EPA registers a pesticide and thereby permits it to be marketed in the United States. FIFRA provides no private cause of action, express or implied, for crop-damage claims related to the inefficacy of pesticides. No evidence suggests that Congress intended to leave the subject of pesticide efficacy completely unregulated by both state and federal governments. A decision that FIFRA preempts state damages actions for efficacy-related claims would have a consequence unintended by Congress and detrimental to the citizens of each of the States: individuals whose crops are wrongfully damaged due to the inefficacy of pesticides would effectively be deprived of any recourse under state or federal law.

SUMMARY OF THE ARGUMENT

FIFRA does not preempt state law crop-injury claims because the text, regulatory framework, and legislative history of the statute reveal no congressional intent to do so. Because of the importance

---

7. *See id.*

of state sovereignty in our federal system of government, the historic police powers of the States are not superseded by federal statute unless it is the clear and manifest purpose of Congress to preempt the States' powers. Because consumer protection law is an area traditionally regulated by the States, compelling evidence of intention to preempt is required. Absent such clear and manifest purpose, the Court should not infer the preemption of state law claims.

FIFRA's text, unlike the text of other federal statutes, contains no language explicitly proscribing the relevant state law at issue—crop-injury actions. The legislative history of the statute also reveals no congressional intent that FIFRA displace state law crop-injury claims. Because Congress has demonstrated that it can speak with "drastic clarity" when it intends to displace state law, and the importance of state sovereignty dictates a strong presumption against preemption in the interpretation of federal statutes, the Court should not conclude that the plain text of FIFRA preempts any state law crop-injury claims.

The regulatory structure of FIFRA, which defines the domain preempted by the statute, also establishes that state law crop-injury claims are not preempted. Congress has given the EPA the role of evaluating and determining the content of pesticide labels under FIFRA; consequently, the EPA's regulations define the domain expressly preempted by the statute. The EPA, however, has affirmatively chosen not to regulate the efficacy of pesticides when it evaluates and approves pesticide labels. Absent such federal regulation, there is no preemption of state law crop-injury claims.

Where Congress has chosen not to provide for federal regulation, the presumption against preemption of state regulation is at its most robust. Here, the federal government does not evaluate efficacy when it permits a pesticide to enter the market and the environment, and, absent a clear statement of congressional

intent to displace state authority—the States retain their traditional authority to provide for consumer protection laws and allow injured farmers a remedy for crop-injury claims.

ARGUMENT

Principles of federalism command congressional respect for the sovereignty of the States, including their authority to render damage judgments in litigation. As the Court has stated, "because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (plurality opinion). This "presumption against preemption" rests on the precept that the Constitution constrains the federal government, the powers of which are limited and specifically enumerated, from trampling on the reserved powers of the States.

This case presents the narrow question whether FIFRA preempts state law crop-injury claims. The text, legislative history, and regulatory framework of FIFRA do not support the conclusion that Congress intended the statute to preempt such claims. The court of appeals's decision preempting the farmers' crop-damage causes of action contravenes the purpose of FIFRA to strengthen the regulation of pesticides, as well as the fundamental precept of federalism that state law will not be deemed displaced absent an explicit congressional mandate.

I. THE TEXT AND REGULATORY FRAMEWORK OF FIFRA DO NOT SUPPORT THE CONCLUSION THAT THE STATUTE PREEMPTS STATE LAW CROP-INJURY CLAIMS.

A. The Court's Analysis Is Guided by the Presumption Against Preemption and the Purpose of Congress in Enacting FIFRA.

The Supremacy Clause prescribes a constitutional choice of law rule that gives federal law precedence over conflicting state law.[8] The Supremacy Clause thus preempts state laws that are inconsistent with federal law. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). Preemption may be express or implied; within implied preemption, the taxonomy further subdivides into field preemption and conflict preemption. Here, the former is at issue, because the language of FIFRA expressly preempts state law:

> "AUTHORITY OF STATES
>
> (a) IN GENERAL.—A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this [Act].
>
> (b) UNIFORMITY.—Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this [Act]." 7 U.S.C. §136v.

The first step in express preemption analysis is to ascertain whether the express preemption provision at issue is "a 'reliable

---

8. *See* U.S. CONST. art. VI, cl. 2 ("This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.").

indicium of congressional intent with respect to state authority.'" *Cipollone*, 505 U.S., at 517 (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 505 (1978)). On its face, the FIFRA preemption provision satisfies this requirement; indeed, it is difficult to envision a more "'reliable indicium of congressional intent with respect to state authority'" than a federal statutory provision entitled "Authority of States." 7 U.S.C. §136v. Preemption analysis should therefore focus on the statutory preemption language because "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." *Id.*, at 517.

Thus, the Court must "'identify the domain expressly pre-empted.'" *Medtronic*, 518 U.S., at 484 (quoting *Cipollone*, 505 U.S., at 517). To do so, the Court begins with FIFRA's text as "informed by two presumptions about the nature of pre-emption." *Id.*, at 484-85. The first presumption is "'that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Id.*, at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). The second longstanding presumption is that "'the purpose of Congress is the ultimate touchstone' in every pre-emption case." *Id.*, at 485 (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)).

A proper analysis must also consider "the 'structure and purpose of the statute as a whole,' as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Id.*, at 486 (quoting *Gade v. Nat'l Solid Waste Mgmt. Ass'n*, 505 U.S. 88, 98 (1992)).

B. The Text of Section 136v and the Overall Regulatory Structure of FIFRA Do Not Provide Clear and Manifest Evidence of Congressional Intent to Preempt Crop-Injury Claims.

By its terms, section 136v establishes five prerequisites to preemption: (1) that there be a state "requirement" (2) "for labeling or packaging," (3) that a State "impose[s] or continue[s] in effect," and that such requirement be (4) "in addition to or different from" (5) a federal requirement under FIFRA. 7 U.S.C. §136v. The farmers' claims under the Texas DTPA and Texas common law do not meet those standards.

1. Crop-Injury Claims Do Not "Impose" a State "Requirement" for Labeling or Packaging.

A jury award of damages to a plaintiff in a crop-injury claim would not require—or even necessarily induce—a manufacturer to change that product's label. In contrast to the statutes considered by the Court in *Cipollone*, FIFRA does not require any particular warning statements about the efficacy of pesticides. Because both the Federal Cigarette Labeling and Advertising Act of 1965[9] and its successor, the Public Health Cigarette Smoking Act of 1969[10] expressly mandated that a specific warning label be affixed on every package of cigarettes sold in the country,[11] a jury

9. 15 U.S.C. §§1331-1339 (1965).

10. 15 U.S.C. §§1331-1340 (1969).

11. Section 4 of the 1965 Act required the following warning to be affixed on every package of cigarettes sold in the country: "Caution: Cigarette Smoking May be Hazardous To Your Health." 15 U.S.C. §1333 (1965). The 1969 Act amended section 4 and mandated the following language: "Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous To Your Health." 15 U.S.C. §1333 (1969).

determination that such label was inadequate left the manufacturer with no choice and no means of escaping liability. The manufacturer would have to either abide by the mandate of the federal statute and be found liable in civil actions filed by consumers—or ignore the federally mandated warning requirement and face enforcement action by the government.

Because FIFRA contains no requirements similar to the cigarette acts regarding the labeling of pesticides as to efficacy, pesticide manufacturers confront no such Hobson's choice. Faced with a jury determination finding inadequate or improper labeling related to pesticide efficacy and crop injury, a pesticide manufacturer would have several feasible and rational alternatives: (1) leave the label, if any, unchanged and absorb the costs of state law crop-damages claims, (2) modify the design or marketing of the product to address the crop-injury problem, or (3) modify the label to accurately reflect the product's efficacy. These choices are not unrealistic in the context of FIFRA, given that Congress enacted the statute to balance the need for continued development of chemical products against the need to protect humans, wildlife, and the environment from unreasonably adverse effects.[12]

Indeed, the Texas farmers' claims in this case exemplify a situation wherein it does not appear that changing the product's label would remedy the problem. The parties do not dispute that Dow's Strongarm product is unsuitable for soils with a pH level of 7.2 or higher. J.A. 181. The record also reflects that the typical soil pH in the peanut farming regions of West Texas is 7.2 or higher. J.A. 125. If the product is unsuitable for an entire region, and perhaps for the soils of other peanut-growing States, it does not

12. *See, e.g.*, 7 U.S.C. §136a(c)(5); *see also* S. REP. NO. 88-573 (1964), *reprinted in* 1964 U.S.C.C.A.N. 2166.

make sense for Dow simply to change the label and tnen continue to sell an ineffective or damaging product in such areas. Rather, it appears the most plausible outcome in this case, if the farmers were successful in their lawsuit, would be for Dow either to modify the product or to cease marketing and selling it in regions where it will harm the crops if utilized by peanut farmers. Neither course of action implicates product "labeling" or "packaging," the limited domain preempted by FIFRA.

The fact that a state law damages award in a crop-injury case could help effectuate the statutory purpose of FIFRA is evident. When damages are minor, a manufacturer required to pay a relatively small amount in compensatory monies is unlikely to choose to alter the product label because the profit margin can absorb the additional costs. In contrast, a manufacturer required to pay substantial amounts of compensatory damages because the product resulted in extensive damages to crops would likely choose to modify or remove the product from the stream of commerce, or modify the marketing or labeling of the product. In this instance, the harm of the product to agriculture would outweigh its value to society. Allowing the state law system to operate in this manner does not render compliance with the regulatory framework of FIFRA impossible, but rather appropriately supplements such regulations.

2. The EPA Does Not Regulate the Efficacy of Pesticides When Approving Pesticide Labels.

Even assuming *arguendo* that the farmers' claims constituted a state "requirement for labeling or packaging" "impose[d] or continue[d] in effect" by the State, preemption must fail because those claims are not "in addition to or different from" any federal requirement under FIFRA. The farmers' claims concern crop injury and Respondent's representations of efficacy, and Congress and the EPA have expressly exempted efficacy in the evaluation of

pesticide labels from the ambit of federal regulation. Absent such federal regulatory coverage, there is no preemption.

FIFRA was originally passed as a labeling statute in 1947, Pub. L. No. 80-104, 61 Stat. 163, requiring registration of pesticides with the Secretary of Agriculture, the display of poison warnings on labels of highly toxic pesticides, and the inclusion of other warning statements to prevent injury to people, animals, and plants. In 1970, authority for pesticide regulation was transferred to the newly-created EPA,[13] which administered the pesticide labeling requirements imposed by the Department of Agriculture. *See* 7 C.F.R. pt. 2762 (1971).

In 1972, FIFRA was strengthened by substantial amendments addressing concerns about health and the environment. The 1972 amendments were designed to give the EPA regulatory authority over the entire process of marketing and selling pesticides. After these extensive revisions, FIFRA was no longer considered merely a labeling law. *Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 601 (1991). Instead, FIFRA was transformed "into a comprehensive regulatory statute." *Id.*, at 598-99. The EPA assumed authority to determine whether, and under what circumstances, a pesticide could be registered for manufacture and sale in the United States. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984). In carrying out the goals of this statute, the EPA determines if, overall, the product represents "an unreasonable risk to man or the environment." 7 U.S.C. §136c(5)c. The statute defines "unreasonable adverse effects on the environment" to mean "any unreasonable risk to man or the environment, taking into account

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13. *See* Reorg. Plan No. 3 of 1970, section 2(8)(i), 35 Fed. Reg. 15,623 (Dec. 2, 1970), *reprinted in* 5 U.S.C. app. at 610 (1970), *and in* 84 Stat. 2086 (1970).

the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. §136(bb).

Under the 1972 amendments to FIFRA, the EPA could register a pesticide only upon evaluating its proposed label and finding that its "composition is such as to warrant the proposed claims for it." 7 U.S.C. §136a(5)(A). The EPA found, however, that it lacked the resources to review all proposed labeling, and that the registration and reregistration process had come to a virtual halt.[14] The EPA reported to Congress that the resources spent evaluating efficacy claims sapped its ability to address fully the concerns of human health and the natural environment that are its most important tasks.[15]

Congress responded to these concerns by amending FIFRA in 1978, expressly granting the EPA authority to waive review of pesticide-efficacy claims: "In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy." 7 U.S.C. §136a(5)(D). This legislation was passed with the express expectation that the EPA would waive review of efficacy data as to agricultural chemicals.[16]

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14. *See* H. REP. NO. 95-663, at 18 (1977), *reprinted in* 1978 U.S.C.C.A.N. 1991.

15. *See* H.R. REP. NO. 95-343, at 9 (1977), *reprinted in* 1978 U.S.C.C.A.N. 1974 (statement of EPA Administrator Douglas M. Costle).

16. *See* H.R. REP. NO. 95-663, at 19 (1977), *reprinted in* 1978 U.S.C.C.A.N. 1992 ("This authority is expected to be used, in particular with respect to agricultural chemicals.").

The EPA subsequently issued a general waiver of the review of labeling claims relating to pesticide efficacy. 40 C.F.R. 158.640(b); 40 C.F.R. 158.540. The EPA explained that the waiver would allow it to focus on its "primary mandate under FIFRA . . . , the health and safety aspects of pesticides." 47 Fed. Reg. 53192, 53196 (Nov. 24, 1982). The EPA decided that efficacy review was unnecessary because efficacy claims are "effectively regulated by the marketplace." 44 Fed. Reg. 27932 (May 11, 1979). Moreover, the EPA expressly noted that,

> "*pesticide producers are aware that they are potentially subject to damage suits* by the user community if their products *prove ineffective* in actual use." 47 Fed. Reg. 40659, 40661 (Sept. 15, 1982) (emphasis added).

Therefore, EPA regulations provide that a pesticide manufacturer need not submit "efficacy" data concerning (1) "target area phytotoxicity," which is defined as whether the pesticide leaves the target crop unharmed, 40 C.F.R. §158.540, or (2) "product performance," defined as whether the pesticide controls the target pest, *id.* §158.640(b).[17]

The EPA has confirmed the absence of federal regulation in this area. In 1996, it issued a public notice explaining that "courts have erroneously concluded that because a pesticide label contained warnings regarding property damage that EPA had necessarily evaluated such warnings and found them to be truthful and adequate

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17. The EPA continues to review pesticide labels regarding "product performance" efficacy data in certain instances involving human health or where the EPA (on a case-by-case basis) requires it. 40 C.F.R. §158.640(b)(1). The EPA regulations also provide that "target area phytotoxicity" data are "required for Special Review and certain public health situations." 40 C.F.R. §158.540. None of these limited circumstances is applicable here.

. . . . [T]his notice is intended to clarify that EPA's approval of a pesticide label does not reflect any determination on the part of EPA that the pesticide will be efficacious or will not damage crops or cause other property damage." Pesticide Registration (PR) Notice 96-4, at 5 (June 3, 1996).

Thus, pursuant to federal regulations, the EPA reviews pesticide labels only for the adequacy of claims relating to human health and the environment—not for "target area phytotoxicity," *i.e.*, the crop-damage claims raised by the farmers in this case. 40 C.F.R. §158.540.

3. The EPA's Regulations Define the Domain Preempted By Section 136v and Confirm That State Law Crop-Damage Claims Are Not Preempted.

The Court has concluded that section 136v of FIFRA resulted in a "narrow pre-emptive overlap" and that Congress did not intend "to occupy the entire field of pesticide regulation." *Mortier*, 501 U.S., at 613. As the Court recognized in *Medtronic*, the preemptive reach of FIFRA is necessarily informed by the scope of agency regulations.[18] In *Medtronic*, the Court determined the preemptive effect of the Medical Device Amendments of 1976 on state-law claims for common-law negligence and strict liability brought against the manufacturer of an allegedly defective pacemaker. 518 U.S., at 474. The Court concluded that defective design claims were not preempted even though the Food and Drug Administration ("FDA") had approved the pacemaker. *See id.*, at 492.

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18. *See* H.R. REP. NO. 92-511, at 1 (explaining that "[t]he Federal Government sets the program standards the States must meet. State authority to change Federal Labeling and packaging is completely preempted" and noting that the EPA has "[g]eneral authority . . . to write regulations to carry out the Act and recognize the use of specialty chemicals").

The Court reached its decision after noting that the FDA "did not 'require' Medtronic's pacemaker to take any particular form for any particular reason; the agency simply allowed the pacemaker, as a device substantially equivalent to one that existed before 1976, to be marketed without running the gauntlet of the [premarket approval] process." *Id.*, at 493-94. As such, the federal requirements did not reflect "an unambiguous conclusion" that was reached after a deliberate weighing of competing interests. *Id.*, at 501. Rather, the requirements "reflect[ed] important but entirely generic concerns about device regulation generally." *Id.*, at 501. Therefore, the recipients' manufacturing and labeling claims were not preempted. *Id.*, at 492.

The Court's decision in *Medtronic* instructs that only when the "Federal Government has weighed the competing interests . . . [and] reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case . . . and implemented that conclusion via a specific mandate" are general state-law claims preempted. *Id.*, at 501. The United States Court of Appeals for the Third Circuit, tracking the Court's *Medtronic* analysis, has concluded that FIFRA does not preempt state-law claims when the EPA has not acted in that particular area. *See Hawkins v. Leslie's Pool Mart, Inc.*, 184 F.3d 244, 254-55 (CA3 1999) (state-law claims related to packaging were not preempted by FIFRA because the EPA did not regulate the packaging methods for the pesticide product at issue).

The Texas Supreme Court reached the same conclusion in *American Cyanamid Co. v. Geye*, 79 S.W.3d 21, 24 (Tex. 2002). The *Geye* court confronted strikingly similar circumstances to those here presented to the Court—crop-damage claims brought by Texas peanut farmers under the Texas DTPA and common law related to the labeling and efficacy of pesticides. *Id.*, at 22-23. The court held that, because Congress has given EPA the role of evaluating and determining the content of pesticide labels under

FIFRA, the EPA's regulations define "'the domain expressly preempted.'" *Id.*, at 24 (quoting *Cipollone*, 505 U.S., at 517). The Texas Supreme Court recognized that, when registering a pesticide and thereby allowing it to be released into the environment, the EPA does not evaluate whether a pesticide product will be toxic to the crops it was intended to assist—and therefore does not regulate a product's labeling claims on this subject. *Id.*, at 29. Because the scope of FIFRA's preemption is dependent on the scope of the statute and the EPA's implementing regulations, the court held that FIFRA did not preempt the farmers' crop-damage claims made under Texas's DTPA and common law. *Id.*

Here, as in *Geye*, the EPA does not consider the efficacy of pesticides in its evaluation of pesticide labels. Because the EPA waived such requirement, there was no EPA or FIFRA labeling "requirement" to preempt Texas's consumer protection statute or the farmers' lawsuit. Under *Medtronic*, allowing state law crop-injury claims—which are brought under a consumer protection statute and based upon claimed inefficacy of the pesticide—will not impose any state-law requirements that are in addition to or different from federal regulations. FIFRA preemption does not sweep so broadly as to hold that state-law claims and the States' consumer protection statutes are preempted in an area that the federal government has chosen not to regulate.

C. The Presumption Against Preemption Applies with Special Force Where the Federal Government Has Chosen Not to Regulate.

The power to supplant state law is "an extraordinary power in a federalist system." *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991). Because this power is capable of upsetting the usual balance of federal and state powers, the Court has assumed that Congress does not exercise that power lightly. *Id.* The Court has

expressed this principle as a presumption against preemption of state law. *See Cipollone*, 505 U.S., at 517-18.

As robust as that presumption is in the ordinary circumstances—where Congress has chosen to regulate and the Court is assessing state requirements concerning the same subject matter—the presumption should be substantially greater where Congress has chosen not to regulate at all.

With apologies to Commerce-Clause jurisprudence, a useful distinction can be drawn between "active" preemption and "dormant" preemption. For the former, where Congress has chosen to extend federal regulation to a specific area where States are likewise regulating, the ordinary presumption against preemption applies. But for the latter, where the federal government has chosen *not* to regulate a particular subject matter, the presumption against preemption is at its apex.

Through the Supremacy Clause, Congress no doubt possesses the authority both (1) to proscribe state regulation in a particular area and (2) to eschew any federal regulation as well. But, such a counterintuitive result should not be readily ascribed to Congress, especially in an area such as the regulation of pesticides where Congress has emphatically recognized the heightened need for adequate regulation.

Thus, were FIFRA to provide something like "notwithstanding the lack of federal regulation of efficacy, no State may prohibit misleading representations of efficacy or otherwise provide remedies for negligent crop damages from pesticides," then preemption would apply. But, absent such an extraordinarily clear statement, there should be no preemption of state authority. *Cf.*

Gregory, 501 U.S., at 460; *Atascadero State Hospital v. Scanlon*, 473 U.S. 234, 239-40 (1985).[19]

Notably, the language of section 136v(b) does not explicitly prohibit state law crop-injury actions, and Congress has shown itself more than capable of expressing unambiguously that state law actions are preempted by federal statutes. For example, the Domestic Housing and International Recovery and Financial Stability Act, 12 U.S.C. §1715z-18(e), states Congress's specific preemptive intent as follows: "Mortgages insured pursuant to this section . . . shall not be subject to any State constitution, statute, court decree, common law, rule, or public policy." Similarly, in the Copyright Act of 1976, 17 U.S.C. §301(b), Congress expressly preempted all legal rights "under the common law or statutes of any State." The preemption language of the Employee Retirement Income Security Act of 1974, 29 U.S.C. §1144(c)(1), is equally explicit: "The term 'State law' includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State." Each of the referenced statutes exemplify the type of language the Court and the States expect Congress to use when it intends to displace state law claims. The absence of the same or similar express preemptive language in FIFRA evidences a lack of clear and manifest congressional intent to displace state law crop-injury claims.

According the presumption against preemption great weight properly renders Congress's displacement of state authority more

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19. In the analogous context of sovereign immunity, the Court has "held that a State will be deemed to have waived its immunity only where stated by the most express language or by such overwhelming implication from the text as [will] leave no room for any other reasonable construction." *Id.* (internal citations omitted) (quoting *Edelman v. Jordan*, 415 U.S. 651, 673 (1974) ((quoting *Murray v. Wilson Distilling Co.*, 213 U.S. 151, 171 (1909))).

difficult by requiring it to speak precisely in express preemption provisions. This requirement enhances legislative accountability, the foundation of our democratic system of governance. And attributing great weight to the presumption maintains federal legislative power, for as the Court has long recognized, "Congress can speak with drastic clarity whenever it chooses to assure full federal authority, completely displacing the States." *Bethlehem Steel Co. v. New York State Labor Relations Bd.*, 330 U.S. 767, 780 (1947). Consistent with these considerations, the presumption against preemption requires extraordinarily clear and manifest evidence of congressional intent to displace the police powers that have historically inhered in the States. *See Cipollone*, 505 U.S., at 516.

Morever, it is particularly significant that the Texas farmers' crop-injury claims were made in part under Texas's statutory consumer protection laws, namely the Texas DTPA, TEX. BUS. & COM. CODE §17.41-.63. J.A. 183. Because consumer protection, and unfair business practices generally, fall squarely within the ambit of the States' historic powers, *see Gen. Motors Corp. v. Abrams*, 897 F.2d 34, 41-42 (CA2 1990), compelling evidence of an intention to preempt is required to preempt state law in these areas. *Id.*; *see also California v. ARC Am. Corp.*, 490 U.S. 93, 101 (1989); *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 146 (1963).

FIFRA's express preemption provision clearly and manifestly indicates congressional intent to preempt state requirements inconsistent with federal labeling and packaging requirements. It does not clearly and manifestly exhibit an intent to displace all state authority, especially where there are no federal requirements because the federal government has not evaluated pesticide efficacy before allowing a manufacturer to release a pesticide into the market and the environment.

II. The Legislative History of FIFRA Confirms that Congress Did Not Intend to Preempt State Law Crop-Injury Claims.

The scope of FIFRA's preemption provision, section 136v, should also be analyzed in the context of the common law at the time of its enactment in 1972. The Court "presume[s] that Congress is knowledgeable about existing law pertinent to the legislation it enacts." *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185 (1988). As Justice Stevens has observed, "[w]e presume that Congress understands the legal terrain in which it operates, . . . and we therefore expect Congress to state clearly any intent to reshape that terrain."[20] *United States v. Texas*, 507 U.S. 529, 540-41 (1993) (Stevens, J., dissenting) (citation omitted). Because state-law actions for crop injury related to pesticide labeling were widely available in 1972, and no evidence indicates that Congress intended to eliminate those actions, the Court should not read section 136v to do so.

A. FIFRA's Legislative History Supports the Conclusion That Congress Did Not Intend to Displace Crop-Injury Claims.

Common-law actions for crop damage related to the inefficacy of pesticides date back to the 19th Century, and were the subject of

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20. *See also Oubre v. Entergy Operations, Inc.*, 522 U.S. 422, 435 (1998) (Thomas, J., dissenting) ("[C]ommon-law doctrines 'ought not to be deemed repealed, unless the language of a statute be clear and explicit for this purpose.'") (quoting *Fairfax's Devisee v. Hunter's Lessee*, 11 U.S. (7 Cranch) 603, 623 (1812)).

numerous reported decisions by 1972.[21] In fact, by 1972, nearly every state and federal jurisdiction had recognized pesticide manufacturer and dealer liability for crop damage (as well as personal injury) related to labeling of products.[22] The Court may therefore presume that Congress was aware that state law crop-damage actions related to the inefficacy of pesticides and labeling of these products were recognized and being brought regularly throughout the United States.

Prior to the passage of the 1972 amendments to FIFRA, Congress held twenty-five days of hearings[23] and issued reports

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21. *See, e.g., Jones v. George*, 61 Tex. 345 (1884) (action against seller of "Royall's Patent or Receipt for Killing Worms," which was represented as effective against cotton worms but failed to control the worms); *White v. Nat'l Bank of Commerce*, 278 P. 915 (Cal. D. Ct. App. 1929) (crop damage action against seller of "Volck Concentrate," falsely represented to control pests without harming citrus trees); *Ebers v. Gen. Chem. Co.*, 17 N.W.2d 176 (Mich. 1945) (action for crop damage caused by inadequately labeled ethylene dichloride emulsion sold to control peach tree borers).

22. *See, e.g., Hubbard-Hall Chem. Co. v. Silverman*, 340 F.2d 402 (CA1 1965) (applying Mass. Law); *Grey v. Hayes-Sammons Chem. Corp.*, 310 F.2d 291 (CA5 1962) (applying Miss. law); *Daniels v. Atlantic Ref. Co.*, 295 F.Supp. 125 (D. Del. 1968) (applying Delaware law); *Gonzalez v. Virginia-Carolina Chem. Co.*, 239 F.Supp. 567 (E.D.S.C. 1965) (applying South Carolina law); *Eaton Fruit Co. v. California Spray-Chem. Corp.*, 445 P.2d 437 (Ariz. 1968); *Diamond Alkali Co. v. Godwin*, 112 S.E.2d 365 (Ga. Ct. App. 1959); *Bean v. Diamond Alkali Co.*, 454 P.2d 69 (Idaho 1969); *Rose v. Buffalo Air Serv.*, 104 N.W.2d 431 (Neb. 1960).

23. *Federal Pesticide Control Act of 1971: Hearings Before the House Comm. On Agric.*, 92nd Cong. (1971); *Federal Environmental Pesticide Control Act of 1971: Hearings before the Subcomm. on Agric.*

from four different committees.[24] At the hearings, what was to become section 136v of FIFRA was extensively discussed. *See, e.g., Federal Pesticide Control Act of 1971: Hearings Before the House Comm. on Agric.*, 92nd Cong. (1971). The EPA's General Counsel testified on behalf of the administration, which drafted the bill that would become the 1972 Amendments to FIFRA:

> "I would like to emphasize that the States have played a major and continuing role in pesticide regulation . . . .We wish to *encourage and not supplant* these efforts by providing that States may prohibit the use of a particular pesticide within their jurisdiction even if the pesticide is registered under the Federal authority. States thus are not precluded from imposing stricter standards or added requirements, but they may not permit any sale or use of a pesticide which is prohibited under the authority of the Act."[25]

Research of the Sen. Comm. on Agric. And Forestry, 92nd Cong. (1971); *Federal Environmental Pesticide Control Act of 1971: Hearings Before the Subcomm. on Agric. Research of the Sen. Comm. on Agric. and Forestry*, 92nd Cong. (1972); *Federal Environmental Pesticide Control Act of 1971: Hearings Before the Subcomm. on the Envt. of the House Comm. on Commerce*, 92nd Cong. (1972).

24. H.R. REP. NO. 92-511 (1971); S. REP. NO. 92-838 (1972), *reprinted in* 1972 U.S.C.C.A.N. 3993, 3993; S. REP. NO. 92-838 (Supplemental Report) (1972); S. REP. NO. 92-970 (1972), *reprinted in* 1972 U.S.C.C.A.N. 3993, 4092; H.R. CONF. REP. 92-1540 (1972), *reprinted in* 1972 U.S.C.C.A.N. 3993, 4130.

25. *Federal Pesticide Control Act of 1971: Hearings Before the House Comm. on Agric.*, 92nd Cong., 1st Sess. (1971) (statement of EPA General Counsel John Quarles) (emphasis added).

The statements of the EPA's General Counsel reflect the overall tenor of the legislative history, which confirms Congress' intent that States continue to play a substantial role in the regulation of pesticides. For example, the Report by the Senate Committee on Agriculture and Forestry noted that enforcement of FIFRA would be strengthened by "authorizing cooperation with States." S. REP. NO. 92-838, at 1 (1972), *reprinted in* 1972 U.S.C.C.A.N. 3993, 3994. The Senate Commerce Committee Report also contained a section entitled "Authority of States" indicating that the intent of the bill was "to leave to the States and local governments the authority to impose stricter regulations on pesticides [sic] use than that [sic] required under the Act." S. REP. NO. 92-970, at 44 (1972), *reprinted in* 1972 U.S.C.C.A.N. 3993, 3994.

Consistent with that manifest intention, six years later, in 1978, Congress expressly authorized the EPA to waive any review of efficacy, 7 U.S.C. §136a(c)(5); and, as the United States conceded in earlier litigation on this same issue, "[i]n authorizing the waiver, Congress anticipated that the states would fill the regulatory gap."[26]

Thus, the legislative history of the 1972 amendments reflects the intent of Congress that the States would act as partners in the regulation of pesticides under FIFRA, and provides no hint of congressional intent to foreclose state-law claims in areas unregulated by the EPA. Indeed, the committee reports issued prior to the passage of FIFRA reveal no intent on the part of Congress to abrogate crop-injury actions under FIFRA. Each report summarizes the changes made by the bill, and none mentions any intent to

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26. U.S. Br., *Etcheverry v. Tri-Ag Service, Inc.*, No. S072524, Cal. Sup. Ct. (Mar. 1999), *available at* https://www.citizen.org/documents/usetcheverrybrief.pdf.

preempt state law crop-injury actions.[27] Likewise, the House and Senate floor debates on the 1972 FIFRA amendments provide no suggestion of a congressional intent to preempt state law crop-injury claims.[28]

B. The Court Should Not Infer Preemption of State Law Tort Claims Based Upon Federal Limitations of Direct Regulations or Positive Enactments of State Governments.

The absence of congressional comment on state law crop-injury claims during passage of the 1972 amendments is significant because it is improper to infer preemption of state law tort claims based upon federal limitations of direct regulations or positive enactments of state governments. As the Court stated when analyzing the similarly-worded preemption provision of the 1965 Cigarette Act in *Cipollone*, "there is no general, inherent conflict between federal pre-emption of state warning requirements and the continued vitality of state common law damages actions." 505 U.S., at 518. Similarly, in *Goodyear Atomic Corp.*, 486 U.S. at 185, the Court recognized the difference between "direct state regulation" and "the incidental regulatory effects" of state common-

27. *See supra* note 23; House Agric. Comm. report at 1-2, 12-13; Sen. Agric. Comm. report at 1-2, 5-6; Sen. Commerce Comm. report, at 8.

28. *See* 117 CONG. REC. 39,975-39,981 (Nov. 8, 1971) (House debate); 117 CONG. REC. 40,020-40,068 (House debate and passage); 118 CONG. REC. 32,448-32, 263 (Sept. 26, 1972) (Sen. debate and passage); 118 CONG. REC. 33,920-33,924 (Oct. 5, 1972) (Sen. passage of conference report); 118 CONG. REC. 35,543-35,547 (Oct. 12, 1972) (House passage of conference report).

law damage awards,[29] concluding that "Congress may reasonably determine that incidental regulatory pressure is acceptable, whereas direct regulatory authority is not."[30] The Court reached a similar conclusion in *English v. General Electric Co.*, 496 U.S. 72 (1990), recognizing that while common-law damages awards could alter behavior, "such an effect would be 'neither direct nor substantial enough' to warrant pre-emption." *Cipollone*, 505 U.S., at 538 (Blackmun, J., concurring in part and dissenting in part) (quoting *English*, 496 U.S., at 85).

As Justice Blackmun noted in his separate opinion in *Cipollone*, state common-law tort claims serve a compensatory purpose separate from their regulatory purpose. *Cipollone*, 505 U.S., at 537 (Blackmun, J., concurring in part and dissenting in part). In fact, the primary purpose of state law claims is compensation, while any regulatory purpose or effect is only incidental. A finding of express preemption of crop-injury claims would leave individuals whose crops were wrongfully harmed by the inefficacy of pesticides without any effective remedy. And an intent to remove all means of redress for an entire class of injured citizens should not lightly be imputed to Congress, absent express indication to the contrary. As the Court noted in a similar context, "[the Atomic Energy Act's] silence takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. It

29. *Id.*, at 185; *see also Cipollone*, 505 U.S., at 536-37 (Blackmun, J., concurring in part and dissenting in part) (distinguishing the direct effect of statutes and administrative regulations from the common law's indirect regulatory effect).

30. *Goodyear*, 486 U.S., at 186; *see also Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 249-56 (1984) (distinguishing the authority of the Nuclear Regulatory Commission from the authority of States to impose tort liability upon those parties falling under the scope of the Nuclear Regulatory Act).

is difficult to believe that Congress would, without comment, remove all means of judicial recourse for [plaintiffs] injured by illegal conduct." *Silkwood*, 464 U.S., at 251.

Because FIFRA does not provide any express or implied private cause of action,[31] the preemption of state law claims in an area unregulated by the EPA effectively removes all recourse for individuals whose crops are damaged due to the inefficacy of a pesticide. In all of the legislative history leading to the passage of section 136v, there is not a single word or comment evidencing a clear and explicit congressional intent to preempt such crop-injury claims. In the absence of explicit federal intent to bar state law crop-injury claims expressed in the text, legislative history, or regulatory structure of FIFRA, the Court should not infer that such claims are preempted.

CONCLUSION

The Court should reverse the judgment of the Fifth Circuit Court of Appeals.

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31. *See, e.g., In re Agent Orange Prod. Liab. Litig.*, 635 F.2d 987, 991-92 n.9 (CA2 1980) (holding that no implied private cause of action exists to recover damages under FIFRA); *Almond Hill Sch. v. United States Dep't of Agric.*, 768 F.2d 1030, 1035-38 (CA9 1985) (stating that "FIFRA does not authorize explicitly or implicitly a private cause of action to enforce the Act.").

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In The
Supreme Court of the United States

DENNIS BATES, et al.,

Petitioners,

v.

DOW AGROSCIENCES LLC,

Respondent.

CORRECTED COPY

On Writ Of Certiorari
To The United States Court Of Appeals
For The Fifth Circuit

BRIEF OF THE TEXAS CHEMICAL COUNCIL AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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QUESTION PRESENTED

Which, if any, state law crop injury claims are preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-137?

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INTEREST OF *AMICUS CURIAE*

Texas Chemical Council (TCC) respectfully files this brief as *amicus curiae*.[1]

TCC is a statewide trade association of businesses operating chemical manufacturing facilities in Texas. TCC has approximately 90 member companies, which operate more than 200 facilities. Texas is the nation's largest producer and exporter of chemical products. Chemical products made by Texans, valued at almost $15 billion dollars annually, are shipped to other countries around the world. In total, chemical products made by Texans are valued at almost $72 billion dollars annually.[2]

In representing the chemical industry, TCC advocates for regulation of the chemical industry based on sound science with clear and cost-effective benefits.[3] TCC has an interest in the question presented by this case because the scope of federal preemption under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 *et seq.* (FIFRA), directly affects the mission of TCC: To create a globally competitive environment for the chemical industry in Texas in a manner that is positive for the state and its people.

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[1] The following representations are made pursuant to Sup. Ct. R. 37: In blanket letters of consent filed with the Clerk, the parties have consented to the filing of *amicus* briefs in this case; no counsel for either party wrote any portion of this brief; no person other than *amicus curiae* made any monetary contribution to the preparation or submission of this brief.

[2] http://www.txchemcouncil.org("Our Industry").

[3] http://www.txchemcouncil.org ("About TCC").

The primary purpose of preemption doctrine is to honor the Supremacy Clause. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). But there is a collateral benefit that is of greater practical importance to private industry: Preemption allows economic actors in the marketplace to regulate their conduct without the threat of conflicting legal obligations, affording certainty for actors who rely on compliance with one set of regulatory standards to protect them from the burdens and inefficiencies of varying state standards. "This policy by itself favors pre-emption of state tort suits, for the rules of law that judges and juries create or apply in such suits may themselves similarly create uncertainty and even conflict, say, when different juries in different States reach different decisions on similar facts." *Geier v. American Honda Motor Co.*, 529 U.S. 861, 871 (2000).

That important economic benefit is undermined if dissatisfied purchasers of chemical products can indirectly call into question federal labeling requirements simply by artfully pleading label-based claims to circumvent federal preemption. TCC respectfully submits this brief in support of the Respondent's position that, correctly understood, all the Petitioners' label-based claims are preempted.

SUMMARY OF ARGUMENT

I. Petitioners' strict liability claims and negligent testing, development, and manufacturing claims are rooted in the allegation that Respondent's herbicide was defectively designed. Under Chapter 82 of the Texas Civil Practice and Remedies Code, every design defect claim must establish the existence of a "safer alternative design."

The statute governs every design defect claim, regardless of form, and it spells out in detail the precise meaning of "safer alternative design" under Texas law.

In this case, Petitioners failed to offer any evidence of a safer alternative design when they were given the opportunity to do so in the district court. Therefore, the courts below properly determined that each of Petitioners' purported design defect claims was functionally a disguised claim for failure to warn. Petitioners cannot avoid preemption by mere artful pleading. Allegations of failure to warn are quintessentially label-related and, as such, are preempted by FIFRA.

II. Petitioners' effort to escape preemption by restating their label-based complaints as off-label claims based on oral representations is equally futile. The lower courts held that these off-label claims are not materially different from the label-based claims, subjecting them to FIFRA preemption. But even if these claims were not preempted, they would not be actionable. The alleged oral representations fall within the traditional rule that mere "puffing" is not actionable. Petitioners cannot escape preemption by recasting their claims into a form that has no independent viability.

III. Finally, Petitioners' claims based on alleged post-sale promises, while not within the scope of FIFRA preemption, are not actionable. Petitioners have given no indication that they could establish the essential elements of those claims. Those claims illustrate the lengths to which Petitioners will go to escape FIFRA, but avoiding preemption on those claims will be an empty victory. The game is not worth the candle.

ARGUMENT

The principal question presented is whether the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 *et seq*. (FIFRA) preempts state-law claims based on alleged defects in product labeling. *Amicus* addresses a related question: Assuming that FIFRA preempts label-based claims arising under state law, may a litigant avoid the scope of that preemption simply by recharacterizing its claim? Put another way, can the Petitioners' claims in this case fairly be characterized as anything other than label-based claims? The answer is "no."

This Court has held "compliance with the intent of Congress cannot be avoided by mere artful pleading." *Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 324 (1981). Litigants cannot evade federal preemption simply by relabeling their claims. *Aetna Health Inc. v. Davila*, 124 S. Ct. 2488, 2498 (2004) (discussing cases). Federal courts addressing FIFRA preemption are not bound by the form of a plaintiff's complaint; they consider the substance of the complaint to determine whether it is, in fact, a label-based claim. If so, the claim is preempted.[4]

[4] *E.g.*, *Netland v. Hess & Clark, Inc.*, 284 F.3d 895, 900 (8th Cir.), *cert. denied*, 537 U.S. 949 (2002); *Andrus v. Agrevo USA Co.*, 178 F.3d 395, 400 (5th Cir. 1999); *Kuiper v. American Cyanamid Co.*, 131 F.3d 656, 666 (7th Cir. 1997); *Grenier v. Vermont Log Bldgs., Inc.*, 96 F.3d 559, 565-66 (1st Cir. 1996); *Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555, 563 (9th Cir. 1995); *Welchert v. American Cyanamid Co.*, 59 F.3d 69, 73 (8th Cir. 1995); *Worm v. American Cyanamid Co.*, 5 F.3d 744, 747-48 (4th Cir. 1993); *Papas v. Upjohn Co.*, 985 F.2d 516, 520 (11th Cir. 1993); *Johnson v. Monsanto Chem. Co.*, 129 F. Supp. 2d 189, 195 (N.D.N.Y. 2001).

This case illustrates the wisdom of that approach. A close examination of the substance of Petitioners' claims reveals that they have no viable cause of action apart from their preempted label-based claims.

I. BECAUSE PETITIONERS FAILED TO OFFER ANY PROOF OF A SAFER ALTERNATIVE DESIGN, ALL THE DESIGN CLAIMS – WHETHER COUCHED IN TERMS OF STRICT LIABILITY, NEGLIGENCE, OR WARRANTY – FAIL ON THEIR OWN TERMS.

The Petitioners suggest that FIFRA preemption of their label-based claims would not likewise preempt their claim that Strongarm was defectively designed, which they characterize as a strict products liability theory, a negligence theory, and a breach of warranty theory. *See* Pet. Br. at 40-44, 47-48.

If there were a legitimate design defect claim, that argument might have merit. But the design defect claims asserted by Petitioners are fatally defective under Texas law: Petitioners have neither identified nor offered competent evidence of a safer alternative design, which is an essential element of any design defect claim. As a result, Petitioners' design claims – whether characterized as strict liability, negligence, or warranty – fail on their own terms. They are simply exercises in artful pleading designed to circumvent the scope of FIFRA preemption. Therefore, the court of appeals correctly concluded that this design defect claim "is functionally a disguised claim for failure to warn." Pet. App. 19a.

A. Regardless of the Form of the Pleadings, All Design Defect Claims Require Proof of the Same Elements.

Although products liability doctrine has its roots in the common law, *see, e.g.*, RESTATEMENT (SECOND) OF TORTS § 402A (1965), the Texas Legislature has acted to displace the common law by codifying specific standards that govern all products liability actions. *See* TEX. CIV. PRAC. & REM. CODE § 82.001 *et seq.* (Vernon 1997).[5] In so doing, the Legislature has mandated that these standards govern every products liability action, regardless of form:

> "Products liability action" means any action against a manufacturer or seller for recovery of damages arising out of personal injury, death, or property damage allegedly caused by a defective product whether the action is based in strict tort liability, strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories.

TEX. CIV. PRAC. & REM. CODE § 82.001(2). Under this statute, "the findings required to establish a design defect claim are identical, regardless of the legal theory asserted." *Hyundai Motor Co. v. Rodriguez*, 995 S.W.2d 661, 664-65 (Tex. 1999). That approach reflects the mainstream view of American tort law. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. n (1998).

As a result, there is no reason to dwell on the semantic distinctions between the Petitioners' strict liability,

[5] For the Court's convenience, the relevant sections of Chapter 82 are set forth in the appendix to this brief.

negligence, and warranty claims. Because each claim is based on an alleged design defect, each claim must satisfy the standards codified in Chapter 82 of the Texas Civil Practice and Remedies Code. They do not.

B. Design Defect Claims Require Proof of a Safer Alternative Design.

In every "products liability action in which a claimant alleges a design defect," the plaintiff bears the burden of proving that "there was a safer alternative design." TEX. CIV. PRAC. & REM. CODE § 82.005(a)(1). The statute specifies a precise definition of "safer alternative design":

> In this section, "safer alternative design" means a product design other than the one actually used that in reasonable probability:
>
> (1) would have prevented or significantly reduced the risk of the claimant's personal injury, property damage, or death without substantially impairing the product's utility; and
>
> (2) was economically and technologically feasible at the time the product left the control of the manufacturer or seller by the application of existing or reasonably achievable scientific knowledge.

TEX. CIV. PRAC. & REM. CODE § 82.005(b).

The "safer alternative design" requirement builds upon the traditional risk-utility test for design defect claims, under which a product is not deemed defectively designed unless it is shown to be unreasonably dangerous. *General Motors Corp. v. Sanchez*, 997 S.W.2d 584, 589 (Tex. 1999). Because a manufacturer is not required to

design the safest possible product, *Acord v. General Motors Corp.*, 669 S.W.2d 111, 114 (Tex. 1984), a design may involve some danger without being defective; only when the risk of a design exceeds its utility can the design be found defective under the risk-utility test. *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 381 (Tex. 1995).

The "safer alternative design" requirement of Chapter 82 supplements this test and makes proof of a safer alternative design a *sine qua non* of design defect law. *See Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 256 (Tex. 1999) ("Section 82.005 reflects the trend in our common-law jurisprudence of elevating the availability of a safer alternative design from a factor to be considered in the risk-utility analysis to a requisite element of a cause of action for defective design."). Petitioners cannot meet that requirement.

C. Petitioners Have Offered No Evidence of a Safer Alternative Design, Underscoring That the Substance of Their Claims Is Label-Based.

As a matter of Texas substantive law, "the burden is on the claimant to prove [the existence of a safer alternative design] by a preponderance of the evidence." TEX. CIV. PRAC. & REM. CODE § 82.005(a)(1); *see also Guaranty Trust Co. v. York*, 326 U.S. 99, 109-10 (1945) ("in diversity cases the federal courts must follow the law of the State as to burden of proof") (citing *Cities Service Oil Co. v. Dunlap*, 308 U.S. 208 (1939)).

Accordingly, in its motion for summary judgment, Respondent challenged Petitioners "to produce evidence in support of their claims" of defective design. R. 312; *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) ("Rule

56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial").

In response, Petitioners offered only the affidavit of Dr. John M. Brown. *See* J.A. 118-127. Dr. Brown offered his opinion that respondent's herbicide "was defective as a herbicide for use in west Texas peanut fields with a soil pH of 7.0 or greater and that the defect in the product rendered the herbicide unreasonably dangerous." J.A. 126. At no point, however, did Dr. Brown address the question of a safer alternative design. By failing to offer any evidence of a safer alternative design to support their purported design defect claims, Petitioners effectively conceded that those claims actually do not constitute design defect claims as a matter of Texas law.

Petitioners' default has two consequences. First, it defeats their design claims, as a matter of law. But more important from the perspective of *Amicus* TCC, Petitioners' default illustrates that their various design claims were nothing more than artful attempts to recast what are, in substance, preempted label-based claims. Here, as in *Quest Chem. Corp. v. Elam*, 898 S.W.2d 819 (Tex. 1995), Petitioners' "*particular* strict liability and [other] claims . . . are based solely upon [the manufacturer's] failure to provide adequate warnings and instructions on its product." *Id.* at 820-21 (emphasis added). Petitioners cannot avoid preemption of these claims by recasting them as design defect claims. *Id.* By any name, Petitioners' products liability claims are label-based.

That conclusion is equally true with respect to the "negligent testing" claim, Pet. Br. at 47-48, which falls within the parameters of a marketing defect claim – not a design defect claim – as a matter of Texas substantive law. *See American Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 437 (Tex. 1997) (holding that a "negligent testing claim is predicated on [defendant's] duty to test and ascertain the dangers inherent in its products about which it must warn consumers"). Thus, the viability of all the Petitioners' strict liability, negligence, and warranty claims, which are inextricably label-based, must stand or fall with the Court's resolution of the preemption question.

II. ANY PRE-SALE REFERENCES TO AN "EXCELLENT" PRODUCT ARE NON-ACTIONABLE "PUFFING" UNDER TEXAS LAW.

Similarly, Petitioners cannot escape preemption of their label-based claims by restating the same allegations as misrepresentations based on pre-sale comments. Petitioners claim violations of the state consumer protection statute (the "DTPA"), breach of warranty, and fraud, based on allegations that a few of them were told the product would be "excellent." *See* Pet. Br. at 44-47. The lower courts held these claims are preempted because the alleged off-label statements were not materially different from the contents of the Strongarm label, subjecting them to the same preemption analysis as the overtly label-based claims. Pet. App. 16a-17a.

Even if the off-label claims were not preempted, they would not be actionable. Texas law distinguishes between actionable misrepresentations of fact and "puffing." The common law has long recognized that the process of selling a product in a competitive market will inevitably involve

giving the product a favorable spin: "It is common knowledge and may always be assumed that any seller will express a favorable opinion concerning what he has to sell; and when he praises it in general terms, without specific content or reference to facts, buyers are expected to and do understand that they are not entitled to rely literally upon the words." RESTATEMENT (SECOND) OF TORTS § 542 cmt. e (1977). Learned Hand nicely articulated the wisdom of the common law:

> The reason of the rule lies, we think, in this: There are some kinds of talk which no sensible man takes seriously, and if he does he suffers from his credulity. If we were all scrupulously honest, it would not be so; but, as it is, neither party usually believes what the seller says about his own opinions, and each knows it. Such statements, like the claims of campaign managers before election, are rather designed to allay the suspicion which would attend their absence than to be understood as having any relation to objective truth.

Vulcan Metals Co. v. Simmons Mfg. Co., 248 F. 853, 856 (2nd Cir. 1918). Today, the Uniform Commercial Code reflects this traditional wisdom in its provision on express warranties, explaining that "affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty." TEX. BUS. & COM. CODE § 2.313(b).

Just as the requirement of a safer alternative design applies to all allegations of design defect, this substantive rule applies to all allegations of misrepresentation. Accordingly, however their misrepresentation claims are framed

in the complaint, Petitioners cannot recover for pre-sale statements that were mere "puffing."

A. "Puffing" Is Not Actionable Under Texas Law.

The common-law rule against imposing liability for mere "puffing" is an established part of Texas fraud law. "Puffery is an expression of opinion by a seller not made as a representation of fact." *Dowling v. NADW Marketing, Inc.*, 631 S.W.2d 726, 729 (Tex. 1982). Statements of puffery or opinion are not fraud. *See, e.g., Transport Ins. Co. v. Faircloth*, 898 S.W.2d 269, 276 (Tex. 1995) ("An actionable representation is one concerning a material fact; a pure expression of opinion will not support an action for fraud."); *Prudential Ins. Co. v. Jefferson Assoc., Ltd.*, 896 S.W.2d 156, 163 (Tex. 1995) ("These statements were not misrepresentations of material fact but merely 'puffing' or opinion, and thus could not constitute fraud.").

Given this strong background rule, the Texas courts have interpreted the state's consumer protection statute (the DTPA) so as to preserve this historical protection for puffing. *E.g., Helena Chem. Co. v. Wilkins*, 47 S.W.3d 486, 502 (Tex. 2001); *Munters Corp. v. Swissco-Young Indus., Inc.*, 100 S.W.3d 292, 298 (Tex. App. – Houston [1st Dist.] 2002, pet dism'd); *Chandler v. Gene Messer Ford, Inc.*, 81 S.W.3d 493, 501 (Tex. App. – Eastland 2002, pet. denied); *Larsen v. Carlene Langford & Assoc.*, 41 S.W.3d 245, 254 (Tex. App. – Waco 2001, pet. denied).

The DTPA affords a statutory remedy for both affirmative misrepresentations and breaches of warranty, TEX. BUS. & COM. CODE § 17.50(a), and the traditional rule against imposing liability for "puffing" applies to both

forms of action. *See, e.g., Kessler v. Fanning*, 953 S.W.2d 515, 519 (Tex. App. – Fort Worth 1997, no pet.); *Humble Nat'l Bank v. DCV, Inc.*, 933 S.W.2d 224, 231 (Tex. App. – Houston [14th Dist.] 1996, writ denied); *Autohaus, Inc. v. Aguilar*, 794 S.W.2d 459, 463 (Tex. App. – Dallas 1990), *writ denied per curiam*, 800 S.W.2d 853 (Tex. 1991).

This is so even though the DTPA makes no mention of protecting "puffing," and it is so in the context of the two specific statutory subsections alleged by the Petitioners as the basis for their claims. As the Texas Supreme Court explains, "The DTPA does not mention 'puffing' as a defense. However, this Court has recognized that 'mere puffing' statements are not actionable under sections 17.46(b)(5) or 17.46(b)(7)." *Helena*, 47 S.W.3d at 502 (citations omitted); *Douglas v. Delp*, 987 S.W.2d 879, 886 (Tex. 1999) ("These subsections are intended to protect consumers against misrepresentations of material fact; statements of opinion alone are generally insufficient to rise to the level of actionable misrepresentations under the DTPA.") (citations omitted).

Therefore, Petitioners cannot recover on any of their misrepresentation claims, whether they are framed as fraud, breach of warranty, or violations of the DTPA, if the pre-sale statements upon which they rely are nothing more than "puffing." Based on the record presented by Petitioners, there is no actionable claim here.

B. References to an "Excellent" Product Are Classic Puffing.

Calling a product "excellent" is quintessential puffing. That is so because the term "excellent" does not connote any objective fact; it is inescapably subjective. Thus,

except in the most unusual circumstances, liability does not fall on one who characterizes a product as "excellent." *E.g.*, *Barber v. Grande Truck Centre, Inc.*, 2002 WL 31253387, *3 (Tex. App. – San Antonio 2002, pet. denied) (unpublished) (representation that vehicle "was of excellent quality and possessed superior performance and driveability" was "mere puffing" and not actionable); *Humble Nat'l Bank v. DCV, Inc.*, 933 S.W.2d 224, 230-31 (Tex. App. – Houston [14th Dist.] 1996, writ denied) (representations by a banker that the bank had a "tradition of excellence" were mere puffing and lacked the specificity required for a warranty); RESTATEMENT (SECOND) OF TORTS § 542 cmt. e (statements "without specific content or reference to facts" are mere puffing).

The Texas Supreme Court applied the traditional rule regarding "puffing" to similar adjectives in *Prudential Ins. Co. v. Jefferson Assoc., Ltd.*, 896 S.W.2d 156 (Tex. 1995), holding that a plaintiff could not recover based on statements that a commercial property was "superb," "super fine," and "one of the finest little properties in the City of Austin." *Id.* at 163. As the Court explained, the statements in question were "not misrepresentations of material fact but merely 'puffing' or opinion." *Id.* That same rule should govern this case.

To be sure, there are rare cases in which the term "excellent" may go beyond mere puffing. *See Pennington v. Singleton*, 606 S.W.2d 682, 687 (Tex. 1980) (statement that boat and motor were "new" or in "excellent" or "perfect" condition were not merely puffing). But *Pennington* is the exception that proves the rule. There, the seller's characterization of the goods as "excellent" was accompanied by a

statement that they were "like new," suggesting an objectively verifiable fact. In fact, the goods were not "like new," but suffered from significant damage. *Id.* Under those unusual circumstances, the term "excellent" when coupled with other representations of quality might be sufficient to move beyond the field of puffing. But such cases are rare indeed, and this does not appear to be one of them.

Fortunately, Texas precedent provides an ideal contrast for the present case, illustrating the degree of specificity and clarity that is needed to exceed "puffing." In *Helena Chem. Co. v. Wilkins*, 47 S.W.3d 486 (Tex. 2001), the Court confronted DTPA claims by farmers against a seed seller based on alleged misrepresentations. The Court exhaustively detailed the alleged misrepresentations, which included numerous and detailed statements about the quality of the product. *Id.* at 502-03. Along with general references to the "excellent" quality of the seed, the Court pointed out that "the Wilkinses' evidence reflects specific representations about Cherokee seed's characteristics and specific representations about how the Wilkinses' crop in particular would perform." *Id.* at 503.

The specificity of the alleged misrepresentations in *Helena Chemical* stands in marked contrast to the generality of the Petitioners' assertions in the present case. Petitioners' claim is limited to a few alleged statements during marketing events (which apparently were not even made to them individually) claiming that "Strongarm was an excellent herbicide to use in West Texas soil for peanuts and weed control." J.A. 152, 157-58; *see also* J.A. 147.

Those alleged statements are classic illustrations of "puffing" under Texas law. They did not include any specific representations concerning the performance of the product in

Petitioners' particular fields, nor did they imply any objective facts. Unlike the exceedingly detailed statements that formed the basis of the claim in *Helena Chemical*, these alleged statements were simply the routine, abstract promotional promises that are made on behalf of every product in the marketplace. Petitioners' complaints about routine marketing statements promoting the "excellent" quality of the product fall squarely within the historical protection for puffing in the marketplace. The term "excellent" is "simply too vague to provide a standard for the jury to use to measure the accuracy of the representation; it is therefore nonactionable." *Bradford v. Vento*, 48 S.W.3d 749, 759 (Tex. 2001).

Petitioners' inability to state viable misrepresentation claims based on alleged off-label statements confirms that the lower courts were correct: Those claims are not materially different from the Petitioners' claims about the contents of the Strongarm label, subjecting them to the same preemption analysis. Pet. App. 16a-17a. Those claims must stand or fall with the Court's resolution of the preemption question.

III. THE ALLEGED POST-SALE STATEMENTS ARE NOT ACTIONABLE.

Finally, Petitioners seek to evade the scope of FIFRA preemption by urging claims based on alleged post-sale promises that Respondent would compensate them for their crop losses. *See* Pet. Br. at 49-50. Respondent acknowledges that these claims are not preempted, but insists that they are without merit. Although the viability of these post-sale claims does not implicate the principal

preemption question presented by this case (and thus does not carry equal importance to *Amicus*) TCC agrees that, as a matter of state law, Petitioners' claims based on the post-sale promises are futile.

Petitioners frame their post-sale claims as fraud, fraudulent inducement, and breach of warranty. *See* Pet. Br. at 49. But Petitioners give no indication that they could establish the essential elements of those claims under Texas law.

To state a fraud claim, Petitioners must prove that they "justifiably relied" on the alleged misrepresentation. *Ernst & Young, L.L.P. v. Pacific Mut. Life Ins. Co.*, 51 S.W.3d 573, 577 (Tex. 2001). That rule bars any claim for damages based on Petitioners' decision to purchase Strongarm, since it is self-evident that they could not have relied upon post-sale representations in their decision to purchase and use the product. "A representation made after a transaction is complete, no matter how false, cannot give rise to an action for fraud." *Eagle Props., Ltd. v. KPMG Peat Marwick*, 912 S.W.2d 825, 827-28 (Tex. App. – El Paso 1995, writ denied) (citing cases).

Petitioners do not assert any other basis for the reliance element of their fraud and fraudulent inducement claims. By their own admission, Petitioners were in a "terrible bind" once the crops had been planted and the growing season had begun. Pet. Br. at 10. Petitioners have failed to show that they took any action in reliance on the post-sale promises that changed their position during the growing season. Because "proof that a party relied to its detriment on an alleged misrepresentation is an essential element of a fraud claim," *Haase v. Glazner*, 62 S.W.3d

795, 798 (Tex. 2001), any claim for fraud or fraudulent inducement is barred.

Likewise, Petitioners' failure to demonstrate reliance bars any warranty claim. "Though not a fraud-based claim, an express warranty claim also requires a form of reliance." *American Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 436 (Tex. 1997); *see also Henry Schein, Inc. v. Stromboe*, 102 S.W.3d 675, 686 (Tex. 2002) (discussing the requirement of reliance in express warranty cases under Texas law); *McManus v. Fleetwood Enterprises, Inc.*, 320 F.3d 545, 550 (5th Cir. 2003) (same). Accordingly, Petitioners have no express warranty claim based on the alleged post-sale promises.

These reliance problems illustrate the circularity of Petitioners' allegations about the post-sale statements: They are simply one more attempt to recast Petitioners' label-based complaints in a different light in order to recover damages. The alleged post-sale promise that Respondent would "pay each Counter-Plaintiff for his loss of profit and all other losses and damages," J.A.190, is a free-standing measure of damages. If it were actionable, it would swallow the entire preemption issue. But there is no reason to believe these claims have any independent viability. Each claim suffers from a fundamental liability flaw, independent of their common reliance element, which would foreclose recovery.

Fraud requires specific intent to deceive at the time the false promise is made, *see Formosa Plastics Corp. U.S.A. v. Presidio Engineers & Contractors, Inc.*, 960 S.W.2d 41, 48 (Tex. 1998), but there is no suggestion in this case that the alleged post-sale promises were made with any intent to deceive. Disgruntled litigants can easily

allege fraud simply by inventing a supposed promise and citing a defendant's failure to honor it as "proof" of fraudulent intent, putting the defendant to a Hobson's choice: Denial of the existence of the promise in the first place becomes "proof" of fraudulent intent. To guard against such opportunistic claims, Texas law requires proof of intent to defraud at the time the promise was made in addition to failure of performance. *Id.* (holding "the mere failure to perform a contract is not evidence of fraud"). Bare allegations of fraud based on nothing more than a failure to perform an alleged promise, like the Petitioners' assertions in this case, do not state a claim for fraud. *See, e.g., Schindler v. Austwell Farmers Co-op.*, 841 S.W.2d 853, 854 (Tex. 1992).

Likewise, Petitioners' fraudulent inducement and express warranty claims fail on their own terms. Petitioners do not suggest that the alleged post-sale promises formed a new contractual relationship between the parties, nor do they allege that these promises formed the basis of the initial bargain. As a matter of Texas law, there can be no fraudulent inducement claim based on a promise that does not ripen into a contract. Fraudulent inducement is "a particular species of fraud that arises only in the context of a contract and requires the existence of a contract as part of its proof." *Haase*, 62 S.W.3d at 798. Similarly, express warranties arise only when a seller makes a promise that forms a "basis of the bargain." TEX. BUS. & COM. CODE § 2.313(a)(1). It is difficult to understand how the alleged post-sale promises could be considered warranties, since they plainly did not form a "basis of the bargain." *Amicus* is unaware of any Texas decision that has adopted such a theory, and it is plainly inconsistent with the requirement of reliance in Texas law. *See*

Compaq Computer Corp. v. LaPray, 135 S.W.3d 657, 675-77 (Tex. 2004).

For all of these reasons, Petitioners' claims for fraud, fraudulent inducement, and breach of warranty based on their allegations of post-sale representations are not viable under Texas law. Those claims appear to be a final manifestation of Petitioners' creative efforts to recast their label-based claims into a form that can escape FIFRA preemption. They may succeed in avoiding FIFRA preemption for these post-sale claims, but it will be an empty victory.

CONCLUSION

The Court should affirm the judgment of the Fifth Circuit Court of Appeals.

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TEX. CIV. PRAC. & REM. CODE § 82.001 – Definitions

In this chapter:

(1) "Claimant" means a party seeking relief, including a plaintiff, counterclaimant, or cross-claimant.

(2) "Products liability action" means any action against a manufacturer or seller for recovery of damages arising out of personal injury, death, or property damage allegedly caused by a defective product whether the action is based in strict tort liability, strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories.

(3) "Seller" means a person who is engaged in the business of distributing or otherwise placing, for any commercial purpose, in the stream of commerce for use or consumption a product or any component part thereof.

(4) "Manufacturer" means a person who is a designer, formulator, constructor, rebuilder, fabricator, producer, compounder, processor, or assembler of any product or any component part thereof and who places the product or any component part thereof in the stream of commerce.

* * *

TEX. CIV. PRAC. & REM. CODE § 82.005 – Design Defects

(a) In a products liability action in which a claimant alleges a design defect, the burden is on the claimant to prove by a preponderance of the evidence that:

(1) there was a safer alternative design; and

(2) the defect was a producing cause of the personal injury, property damage, or death for which the claimant seeks recovery.

(b) In this section, "safer alternative design" means a product design other than the one actually used that in reasonable probability:

(1) would have prevented or significantly reduced the risk of the claimant's personal injury, property damage, or death without substantially impairing the product's utility; and

(2) was economically and technologically feasible at the time the product left the control of the manufacturer or seller by the application of existing or reasonably achievable scientific knowledge.

(c) This section does not supersede or modify any statute, regulation, or other law of this state or of the United States that relates to liability for, or to relief in the form of, abatement of nuisance, civil penalties, cleanup costs, cost recovery, an injunction, or restitution that arises from contamination or pollution of the environment.

(d) This section does not apply to:

(1) a cause of action based on a toxic or environmental tort as defined by Sections 33.013(c)(2) and (3); or

(2) a drug or device, as those terms are defined in the federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 321).

(e) This section is not declarative, by implication or otherwise, of the common law with respect to any product and shall not be construed to restrict the courts of this state in developing the common law with respect to any product which is not subject to this section.

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v.

DOW AGROSCIENCES LLC,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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BRIEF FOR *AMICUS CURIAE* WASHINGTON LEGAL FOUNDATION IN SUPPORT OF RESPONDENT

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INTEREST OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a public interest law and policy center based in Washington, D.C., with supporters nationwide.[1] While WLF engages in litigation and administrative proceedings in a variety of areas, WLF devotes a substantial portion of its resources to defending free enterprise, individual rights, and a limited and accountable government. To that end, WLF has frequently appeared as *amicus* in this Court and lower courts to address the proper scope of federal preemption. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Geier v. American Honda Co.*, 529 U.S. 861 (2000); *Greater N.Y. Metro. Food Council v. Giuliani*, 195 F.3d 100 (2nd Cir. 1999); *Lindsey v. Tacoma-Pierce County Health Dept.*, 195 F.3d 1065 (9th Cir. 1999); *Taylor v. SmithKline Beecham Corp.*, 468 Mich. 1, 658 N.W.2d 127 (Mich. 2003); *Etcheverry v. Tri-Ag Services*, 22 Cal. 4th 316, 993 P.2d 366 (Cal. 2000). WLF has no interest, financial or otherwise, in the outcome of this lawsuit.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case presents the Court with the opportunity to affirm the longstanding interpretation of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 *et seq.* ("FIFRA"), as preempting state law actions based on alleged mislabeling. FIFRA has been interpreted as preempting all such claims by a virtually unbroken line of federal appeals court and state supreme court decisions over the past twenty years.[2]

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[1] Pursuant to Supreme Court Rule 37.6, *amicus* states that no counsel for any party authored this brief in whole or in part, and that no person or entity, other than *amicus* and its counsel, contributed monetarily to the preparation or submission of this brief. The parties have consented to the filing of all *amicus* briefs; pursuant to Supreme Court Rule 37.3, letters evidencing this consent have been filed with the Clerk.

[2] Respondent's Br. at 26-28; Amicus Br. of Association of Trial Lawyers of America at 1, 10-11.

Congress has never acted to overturn this consistent interpretation. A contrary ruling by this Court would upset the settled expectations of stakeholders, particularly insurers and reinsurers that have implicitly incorporated the rule into the premiums for already-issued liability policies.

As further detailed below, if this Court were to change the current national policy on FIFRA preemption, the effect of such a holding would be to frustrate three important congressional and Executive Branch objectives. First, it would frustrate the congressional intent that enforcement of pesticide labeling standards would be tempered by prosecutorial discretion to assure that enforcement actions are proportionate to the harm and are consonant with the needs of the agricultural sector. Second, it would frustrate the congressional intent embodied in Federal Rule of Evidence 407 in favor of promoting continuous self-improvement measures by industry, including improvements in product labeling. Finally, it would frustrate current Executive Branch policies in favor of harmonizing U.S. pesticide labeling standards with recently-adopted global standards.

ARGUMENT

I. Congress Determined In FIFRA That EPA, and EPA Alone, Would Set Policy As To Pesticide Misbranding Standards And Enforcement

In enacting FIFRA, Congress vested EPA with a panoply of enforcement powers, backed by both civil and criminal penalties. Congress directed EPA to exercise these powers with prosecutorial discretion, taking into account the potential consequences of its actions with regard to a pesticide, including effects on the agricultural economy and retail food prices. The sweeping standard-setting authority granted to the EPA in the area of pesticide labels, and the discretionary character of the enforcement powers created by Congress, reinforces the

preemption provision of 7 U.S.C. § 136v(b):[3] An unrestricted ability of plaintiffs' lawyers to bring label-based actions under state law would plainly undermine the stated intent of Congress with regard to standard-setting and enforcement. It would sweep away both the exclusivity of federal regulation and the policy considerations that Congress expected would drive and restrain enforcement activity.

The congressional intent of *federal* policymaking and *discretionary* enforcement strongly counsels against upsetting the longstanding judicial interpretation of § 136v as preempting state law actions. Indeed, this Court has indicated that even in the absence of an explicit preemption provision in a federal statute, it is "not enough to say that the ultimate goal of both federal and state law" is the same; "state law also is preempted if it interferes with the methods by which the federal statute was designed to reach this goal." *International Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987). A proliferation of state law actions based on alleged labeling violations would interfere with the approach chosen by Congress with regard to FIFRA enforcement.

FIFRA makes it unlawful to sell any "misbranded" pesticide. 7 U.S.C. § 136j(a)(1)(E). The statute sets out a detailed definition of "misbranded" at § 136(q), and EPA has set out even more detailed requirements for pesticide labeling at 40

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[3] Section 136v provides as follows in pertinent part:

> § 136v Authority of States
> (a) In general
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.
> (b) Uniformity
> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

7 U.S.C. § 136v(a) & (b).

C.F.R. Part 156. In support of these statutory and regulatory requirements, EPA has the authority to forbid the sale or use of any pesticide if it has "reason to believe" the pesticide is in violation. 7 U.S.C. § 136k(a). EPA also has the authority to proceed in federal district court to confiscate any misbranded pesticide, including in cases where the labeling conforms to federal requirements and the pesticide "nevertheless causes unreasonable adverse effects on the environment." 7 U.S.C. § 136k(b)(3).

EPA may cancel the registration of a pesticide where the product "when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." 7 U.S.C. § 136d(b). Congress specifically directed, however, that the agency take policy considerations into account in weighing whether to seek cancellation. In particular, EPA must seek the advice of the Secretary of Agriculture and must finally "include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. . . ." *Id.*

EPA may impose substantial civil or criminal penalties for any violation of FIFRA or EPA's regulations under the statute. 7 U.S.C. §§ 136*l*(a) & (b). Pesticide makers are subject to civil penalties of up to $5,000 per offense. Here, too, Congress has directed EPA to exercise discretion. "In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation." 7 U.S.C. § 1361*l*(a)(4).

Congress further made clear its expectation that EPA will use prosecutorial discretion by stating that "[n]othing in this Act shall be construed as requiring the Administrator to institute proceedings for prosecution of minor violations of this Act whenever the Administrator believes that the public interest will

be adequately served by a suitable written notice of warning." 7 U.S.C. § 136g(c)(3).

Each of these provisions calling for calibrated enforcement would effectively become a dead letter under the theory advanced by Petitioners. The federal program, with its mandate to take into account nationwide agricultural and economic considerations, would take a back seat to claims filed under the varied laws of the states – claims limited not by policy concerns, but by the ability of plaintiffs' lawyers to recruit claimants. As the Supreme Court of Texas recognized in *Delta Air Lines, Inc. v. Black*, 116 S.W.3d 745 (Tex. 2003), where a federal administrative enforcement program is already in place with respect to certain conduct, allowing state law claims to go forward means the affected industry "would potentially be subject to regulation by fifty different states" and "could create extensive multi-state litigation launching inconsistent assaults on federal deregulation. . . ." *Id.* at 756.

II. The Public Policy In Favor of Preemption of State Law Claims Based on Labeling Is Particularly Strong Where, As Here, The Claim Is Based On Subsequent Label Improvements.

Federal Rule of Evidence 407 is meant to avoid the scenario in which businesses fear taking measures to improve the quality and safety of their products out of concern for tort liability. By excluding evidence in federal cases based on corrective measures or product improvements, Rule 407 embodies a federal policy that fostering higher quality and safety should take precedence over assuring a civil remedy in some cases. Where, as here, a labeling claim is based on exactly such a corrective measure, Pet. App. 30a, FIFRA's preemption provision should be read in light of the policy in Rule 407.

Rule 407, "Subsequent Remedial Measures," provides as follows:

> When, after an injury or harm allegedly caused by an event, measures are taken that, if taken previously, would have made the injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove negligence, culpable conduct, a defect in a product, a defect in a product's design, or a need for a warning or instruction. This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving ownership, control, or feasibility of precautionary measures, if controverted, or impeachment.

The rule codifies the "conventional doctrine which excludes evidence of subsequent remedial measures as proof of an admission of fault." Notes of Advisory Committee Rules. When a manufacturer takes action to improve a product, whether it be changes to the product, changes in policy, or changes to warning labels, such action cannot be introduced as evidence to prove negligence or culpability for damages resulting from use of that product prior to the action. As the Seventh Circuit has noted, "The major purpose of Rule 407 is to promote safety by removing the disincentive to make repairs (or take other safety measures) after an accident that would exist if the accident victim could use those measures as evidence of the defendant's liability." *Flaminio v. Honda Motor Co.*, 733 F.2d 463, 467 (7th Cir. 1984). *See also Raymond v. Raymond Corp.*, 938 F. 2d 1518, 1523 (1st Cir. 1991).

Rule 407 applies of its own force, naturally, in federal court actions (though its independent application to the present case is not before this Court). Whether or not Rule 407 applies of its own force in a given case, there is a strong public interest in preventing plaintiffs from using evidence of remedial measures as a sword against manufacturers. The policy that Rule 407 sets out thus favors the long-time interpretation of FIFRA as preempting state law actions.

III. The Public Policy In Favor of Preemption of State Law Claims Based On Labeling Is Particularly Strong Where, As Here, Inconsistent State Standards Would Thwart Federal Policy On Harmonization With Global Labeling Standards.

The Globally Harmonized System of Classification and Labelling of Chemicals ("GHS") is the result of a global effort to harmonize "major existing systems for chemicals in transport and in the workplace, pesticides, and consumer products, without lower the level of protection afforded by those existing systems." *The Globally Harmonized System of Classification and Labelling of Chemicals (GHS): Implementation Issues for the Office of Pesticide Programs* 2 (Draft July 7, 2004) (hereinafter *GHS Implementation Issues*).[4] United States Government positions in the development and negotiation of GHS – an effort spanning a decade – were determined "by an interagency group consisting of key regulatory and trade agencies and led by the State Department." *Id.* at 4.

EPA has announced its intent to implement GHS. GHS is a voluntary international system; its implementation by EPA is not founded on treaty obligations, but instead on U.S. federal policy considerations. EPA has stated that in its view, global consistency in labeling "will promote greater clarity and understanding of the hazards of pesticide products, thereby reducing potential hazardous exposures and adverse effects from use. . . ." *Pesticides; Implementation of Globally Harmonized System; Notice of Availability*, 69 Fed. Reg. 52,262 (Aug. 25, 2004). EPA also expects that harmonizing U.S. labeling requirements with global standards "will reduce costly and time-consuming activities needed to comply with multiple

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[4] Available for download at *http://www.epa.gov/oppfead1/international/global/globa-whitepaper.pdf*.

international classification and labeling systems, promoting more consistency in regulation, and reducing non-tariff barriers to trade." *Id.* at 52,264. EPA intends to implement GHS with respect to all FIFRA-covered pesticides and to adopt GHS criteria for classifying hazards as well as GHS label elements. *GHS Implementation Issues, supra,* at 12.

National uniformity of pesticide labeling regulation is thus of even greater significance today than it was when FIFRA was enacted in 1972. The United States Government cannot speak with one voice in negotiations over labeling standards if every federal policy – including a policy of embracing a deregulatory approach toward some label content – may be overridden by a jury in a state law action. Conflicting standards in state law actions would thwart the hoped-for benefits of reducing compliance costs from multiple international classification and labeling systems and of reducing non-tariff barriers to trade.

CONCLUSION

For the foregoing reasons, the Court should affirm the judgment of the court of appeals.

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BRIEF FOR THE WESTERN PEANUT GROWERS ASSOCIATION, CORN PRODUCERS ASSOCIATION OF TEXAS, TEXAS PEANUT PRODUCERS BOARD, AND EVERGREEN FARMS IN SUPPORT OF PETITIONERS

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STATEMENT OF INTEREST*

The Western Peanut Growers Association is a nonprofit trade association representing approximately 1,000 peanut growers in legislative and public policy matters. The Texas Peanut Producers Board is the oldest commodity board in Texas, representing the interests of peanut producers in improving peanut quality and improving the profitability of peanut production. The Corn Producers Association of Texas is a nonprofit trade group representing approximately 250 corn producers, committed to increasing the profitability of corn production through education, promotion, research, and marketing. Evergreen Farms is a vegetable and pecan farm operated by Howard Ivy.

These *amici* represent farmers who purchase and use pesticides and other agricultural chemicals. They have a strong interest in the question presented by this case, as their ability to recover for injuries they may suffer as a result of using pesticides may depend on the preemptive effect of 7 U.S.C. § 136v(b). As we demonstrate below, by the time the statute was enacted in 1972, farmers and others injured by pesticides had for decades maintained actions against pesticide manufacturers under theories of breach of duty to warn, failure to perform as advertised, breach of warranty, strict liability, and other common law theories. Nothing in the statutory text or the voluminous legislative history suggests than Congress intended to deprive them of their long-established common-law remedies.

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* Pursuant to Rule 37.6, *amici* state that no counsel for any party authored any part of this brief. No person or entity, other than *amici*, made a monetary contribution toward the preparation or submission of this brief, which is filed with the parties' written blanket consent.

INTRODUCTION AND SUMMARY OF ARGUMENT

The issue presented by this case is whether Congress intended to extinguish damages actions under state common law by prohibiting the states from imposing pesticide labeling "requirements," as that term is used in Section 24(b) of the Federal Environmental Pesticide Control Act of 1972 ("1972 Act"), codified at 7 U.S.C. § 136v(b). In *Cippolone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), and *Medtronic v. Lohr*, 518 U.S. 470 (1996), this Court interpreted two different federal statutes that prohibit states from imposing certain types of "requirements," and reached differing conclusions as to whether those prohibitions encompass common law damages actions. Although *Cippolone* and *Medtronic* construe the term "requirements" differently, the cases teach the same lesson: the meaning of the term "requirements" must be inferred from its statutory context. "Only mischief" can result from giving terms in different statutes "one meaning regardless of the statutory context." *Lee v. Madigan*, 358 U.S. 228, 231 (1959).

An examination of the statutory context of Section 136v(b) reveals that Congress had no intention in enacting the 1972 Act to preempt any common law damage remedies. Section 136v is addressed to a question very different from the continued availability of tort remedies: the scope of state agencies' authority to regulate pesticides in light of the expansion of federal authority carried out in the 1972 Act. Under the Federal Insecticide, Fungicide, and Rodenticide Act of 1947, 61 Stat. 163 ("1947 Act"), the federal government had regulated the content of labels of pesticides that traveled in interstate commerce by requiring that such pesticides be registered with the Department of Agriculture, a process that required federal approval of the form and content of pesticide labels, but pre-1972 federal law did not require registration for pesticides that moved only in intrastate commerce, nor did it directly regulate the use of any

pesticides.[1] These subjects were within the purview of state agencies, which had established a variety of regulatory schemes governing pesticide uses and which also required registration and approval of labels for pesticides formulated for in-state use.[2] In the 1972 Act, the federal government moved into these areas previously regulated by state agencies, raising the question of what regulatory authority state administrative agencies retained.

Section 24 of the 1972 Act, codified at Section 136v, represents Congress's principal effort to answer that question. Subsection (a) of that provision, aptly entitled, "In general," establishes the general rule that state agencies "may regulate" the uses of pesticide to the extent such regulation is stricter than that imposed by EPA. Subsection (b) is entitled "Uniformity" because it addresses the interest in allowing pesticide manufacturers to market pesticides nationally bearing a single uniform label. It establishes an exception to the general rule—"such states," *i.e.*, those which regulate the *use* of pesticides, may not impose labeling "requirements" different from those mandated by EPA. Subsection (c), in turn, provides that, notwithstanding the general prohibition on state-imposed labeling requirements, a state may require registration of pesticides formulated for use within that state to allow "additional uses" of the pesticides not approved by the federal government to "meet special local needs." Under subsection (c), states may approve supplemental labels giving instructions and warnings regarding these additional uses,

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[1] *See* 7 U.S.C. § 135b (repealed); S. Rep. No. 838, 92d Cong., 2d Sess. (1972) ["Sen. Ag. Comm. Report"] at 4 ("[T]here is no prohibition at present against the misuse of a registered pesticide. There is also no control under the Act for pesticides distributed within a single state.").

[2] *See* Federal Pesticide Control Act of 1971: Hearings Before the House Comm. on Ag., 92d Cong., 1st Sess. (1971) ["House Comm. Hearing"] at 21-22 (table of state pesticide laws).

and, in doing so, states impose regulatory requirements regarding the form and content of those labels.[3]

Section 136v(b) cannot be construed to eliminate existing common law damages remedies because there is no basis for believing that Congress even *considered* doing so (let alone *intended* to do so). At the time of the enactment of the 1972 Act, common law damages actions against pesticide manufacturers sounding in tort were a commonplace and uncontroversial feature of the legal landscape, and hundreds of cases had been decided involving claims that instructions and warnings provided by pesticide companies were inadequate, misleading, or false, and allegations that a pesticide failed to live up to claims made on a pesticide label. Although state and federal statutes had long imposed substantial pesticide labeling requirements, these requirements were not understood to conflict in any way with the availability of common law damages actions against pesticide manufacturers based on their failure to warn, fraudulent misrepresentations, or other tortious conduct.

The conclusion that Section 136v(b) is addressed exclusively to the respective authority of state and federal administrative agencies, and not the availability of common law damages actions, is overwhelmingly demonstrated by the legislative history of the 1972 Act. All the testimony, debates, and discussions over what became Section 136v(b) address the ongoing regulatory authority of the state pesticide agencies. In contrast, in 2300 pages of committee hearing transcripts regarding the 1972 Act, four committee reports, a conference committee report, and five days of debate on the

[3] *See* 40 C.F.R. § 162.153(e). For examples of state labeling requirements, *see, e.g.*, Cal. Admin. Code tit. 3, § 6235-6243; La. Admin Code. tit. 7, pt. XXIII, § 117; 7 Pa. Admin. Code § 128.92; 333 Mass. Admin. Code § 8.04; Wash. Admin. Code § 16-228-1400. *See generally* Donald Stever, 1 Law of Chemical Reg. and Hazardous Waste §§ 3:46-3:48 (2004).

floor of the House and Senate, there is absolutely *no* discussion of extinguishing common law damages remedies. Congress should not be deemed to have wiped out, without ever having considered the question, a body of important remedies that had long been available to persons injured by pesticides.

ARGUMENT

CONGRESS DID NOT INTEND TO PREEMPT COMMON LAW DAMAGE ACTIONS IN ENACTING 7 U.S.C. § 136v(b)

A. When Congress Enacted Section 136v(b), Common Law Damages Actions Challenging the Adequacy of Warnings and Label Statements Made By Pesticide Manufacturers Were Widely Available Notwithstanding Extensive Pesticide Labeling Requirements

In order to understand the changes made (and not made) in pesticide regulation through the 1972 Act, it is important to understand the state of the law as it existed in 1972, as it must be "presume[d] that Congress is knowledgeable about existing law pertinent to the legislation it enacts." *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185 (1988). *See also Miles v. Apex Marine Corp.*, 498 U.S. 19, 32 (1990); *Cannon v. University of Chicago*, 441 U.S. 667, 698-99 (1979). The 1972 Act should be read to alter existing law, including the availability of common law damages actions, only if there is substantial reason to believe that Congress intended that result. *See, e.g., United States v. Texas*, 507 U.S. 529, 534 (1993) (discussing the "longstanding . . . principle" that "statutes which invade the common law . . . are to be read with a presumption favoring the retention of long-established and familiar principles"); *Norfolk Redevelopment and Housing Auth. v. Chesapeake & Potomac Tel. Co.*, 464 U.S. 30, 35-36 (1983) (common-law doctrines "'ought not to be deemed repealed, unless the language of the statute be clear

and explicit for this purpose.' ") (quoting *Fairfax's Devisee v. Hunter's Lessee*, 7 Cranch 603, 623 (1812)); *Mobil Oil Corp. v. Higginbotham*, 436 U.S. 618, 625 (1978) (statute must "speak directly" to abrogate common law principle). "[T]his presumption favoring retention of existing law" is particularly appropriate where, as here, the settled law in question is *state* common law. *United States v. Texas*, 507 U.S. at 543 (citing *Milwaukee v. Illinois*, 451 U.S. 304, 316-17 (1981)).

1. *At the time of the enactment of the 1972 Act, common law damages actions against pesticide manufacturers were widely available and uncontroversial*

To construe Section 136v(b), as did the court of appeals, as preempting any state common law damages action that touches on the adequacy or inadequacy of statements made on pesticide labels (not to mention those which might operate indirectly, to "induce" manufacturers to alter their labels), would eliminate a large and settled body of law. Since the late nineteenth century, common law damages actions have been available to those injured by ineffectual or harmful pesticides.[4] In 1884, a farmer brought an action against the seller of "Royall's Patent or Receipt for Killing Worms," which had been represented as effective against cotton worms but which plaintiff allegedly had failed to control them.[5] Since then, pesticide manufacturers were held to answer under familiar tort theories for failure to warn of the potential harms to crops

[4] The issue here differs from that in *Cippolone*, which addressed whether Congress intended to preempt tort actions against cigarette manufacturers. When the statutes involved in *Cippolone* were adopted, there had been almost no history of common law actions against cigarette manufacturers. *See* Robert L. Rabin, *A Sociolegal History of the Tobacco Tort Litigation*, 44 Stan. L. Rev. 853 (1992).

[5] *Jones v. George*, 61 Tex. 345 (1884).

and farm animals resulting from use of their products,[6] and for personal injuries resulting from use of their products.[7]

In addition to actions for failure to warn, pesticide manufacturers were long subject to suit on a variety of other common law theories when their products failed to perform as advertised or otherwise caused injury. Manufacturers thus were held to a standard of strict liability for manufacturing products that failed to perform as advertised.[8] They also faced liability for negligence in formulating products that

[6] *See, e.g., E.I. Du Pont de Nemours & Co. v. Baridon*, 73 F.2d 26 (8th Cir. 1934); *Reasor-Hill Corp. v. Kennedy*, 272 S.W.2d 685 (Ark. 1954); *White v. National Bank of Comm.*, 278 P. 915 (Cal. D. Ct. App. 1929); *Daniels v. Atlantic Refining Co.*, 295 F. Supp. 125 (D. Del. 1968); *Larance v. FMC Corp.*, 192 So. 2d 628 (La. App. Ct. 1966); *Ebers v. General Chem. Co.*, 17 N.W.2d 176 (Mich. 1945); *Streich v. Hilton-Davis*, 692 P.2d 440 (Mont. 1984); *Dole v. Dow Chem. Co.*, 316 N.Y.S.2d 348 (N.Y. Sup. Ct. 1970); *Swift & Co. v. Phillips*, 314 S.W.2d 326 (Tex. Civ. App. 1958); *McClanhan v. Cal. Spray-Chem Corp.*, 75 S.E.2d 712 (Va. 1953); *Golden Gate Hop Ranch, Inc. v. Velsicol Chem. Corp.*, 403 P.2d 351 (Wash. 1965).

[7] *See, e.g., Hubbard-Hall Chemical Co. v. Silverman*, 340 F.2d 402 (1st Cir. 1965); *West Disinfecting Co. v. Plummer*, 44 App. D.C. 345 (D.C. Cir. 1916); *Griffin v. Planters Chem. Corp.*, 302 F. Supp. 937 (D.S.C. 1969); *Gonzalez v. Virginia-Carolina Chemical Co.*, 239 F. Supp. 567 (D. S.C. 1965); *Boyl v. California Chemical Co.*, 221 F. Supp. 669 (D. Or. 1963); *Edwards v. California Chemical Co.*, 245 So. 2d 259 (Fla. Ct. App. 1971); *Weber v. Fidelity & Casualty Ins. Co.*, 250 So. 2d 754 (La. 1971); *McCrossin v. Noyes Bros. & Cutler*, 173 N.W. 566 (Minn. 1919); *Orr v. Shell Oil Co.*, 177 S.W.2d 608 (Mo. 1943); *Muncy v. Magnolia Chem. Co.*, 437 S.W.2d 15 (Tex. Ct. App. 1968); *Rumsey v. Freeway Manor Minimax*, 423 S.W.2d 387 (Tex. Ct. App. 1968); *Mossrud v. Lee*, 157 N.W. 758 (Wisc. 1916).

[8] *See, e.g., Chapman Chemical Co. v. Taylor*, 222 S.W.2d 820 (Ark. 1949); *Stiltjes v. Ridco Exterminating Co.*, 347 S.E.2d 568 (Ga. 1986); *Streich v. Hilton-Davis*, 692 P.2d 440 (Mont. 1984); *Rose v. Buffalo Air Serv.*, 104 N.W.2d 431 (Neb. 1960).

caused personal injuries or harm to crops,[9] and for failing to conduct testing sufficient to ensure their products' safety and efficacy.[10] Manufacturers were also understood to sell pesticides subject to implied warranties of fitness and merchantability, and could be liable as well when products failed to perform as expressly warranted.[11]

The availability of common law actions against pesticide manufacturers is richly documented in a lengthy 1962 anno-

[9] *See, e.g., Grey v. Hayes-Sammons Chemical Co.*, 310 F.2d 291 (5th Cir. 1962); *Branco Eastern Co. v. Leffler*, 482 P.2d 364 (Colo. 1971); *Great Western Oil Co. v. Kraus*, 122 N.E. 12 (Ind. Ct. App. 1919); *Weber v. Fidelity & Casualty Ins. Co.*, 250 So. 2d 754 (La. 1971); *La Plant v. E.I. Du Pont de Nemours & Co.*, 346 S.W.2d 231 (Mo. Ct. App. 1961); *Corprew v. Geigy Chemical Corp.*, 157 S.E.2d 98 (N.C. 1967); *Simpson v. American Oil Co.*, 8 S.E.2d 813 (N.C. 1940); *Patterson v. Orangeburg Fertilizer Co.*, 108 S.E. 401 (S.C. 1921); *Wise v. Hayes*, 361 P.2d 171 (Wash. 1961); *Perry Creek Cranberry Corp. v. Hopkins Ag. Chem. Co.*, 139 N.W.2d 96 (Wisc. 1966); *Smith v. Atco Co.*, 94 N.W.2d 697 (Wisc. 1959).

[10] *E.g., Gonzalez v. Virginia-Carolina Chem. Co.*, 239 F. Supp. 567 (D. S.C. 1965); *Reasor-Hill Corp. v. Kennedy*, 272 S.W.2d 685 (Ark. 1954); *Chapman Chem. Co. v. Taylor*, 222 S.W.2d 820 (Ark. 1949); *Ebers v. General Chem. Co.*, 17 N.W.2d 176 (Mich. 1945).

[11] *See, e.g., McQuaide v. Bridgeport Brass Co.*, 190 F. Supp. 252 (D. Conn. 1960); *Van Antwerp-Aldridge Drug Co. v. Schwartz*, 82 So. 2d 209 (Ala. 1955); *Eaton Fruit Co. v. California Spray-Chem. Corp.*, 445 P.2d 437 (Ariz. 1968); *Burr v. Sherwin Williams Co.*, 268 P.2d 1041 (Cal. 1954); *Sawan, Inc. v. American Cyanamid Co.*, 88 S.E.2d 152 (Ga. 1955); *Diamond Alkali Co. v. Godwin*, 112 S.E.2d 365 (Ga. Ct. App. 1959); *Bean v. Diamond Alkali Co.*, 454 P.2d 69 (Idaho 1969); *Ducote v. Chevron Chem. Co.*, 227 So. 2d 601 (La. Ct. App. 1969); *Ebers v. Gen'l Chem. Co.*, 17 N.W.2d 176 (Mich. 1945); *Corprew v. Geigy Chem. Corp.*, 157 S.E.2d 98 (N.C. 1967); *Simpson v. American Oil Co.*, 8 S.E.2d 813 (N.C. 1940); *Patterson v. Orangeburg Fert. Co.*, 108 S.E. 401 (S.C. 1921); *Swift & Co. v. Bennett*, 373 S.W.2d 569 (Tex. Civ. App. 1963); *Wasatch Chem. Co. v. Leon*, 259 P.2d 301 (Utah 1953); *Udell v. Rohm & Haas Co.*, 392 P.2d 225 (Wash. 1964); *Ingraham v. Assoc. Oil Co.*, 6 P.2d 645 (Wash. 1932); *Dobias v. Western Farmers Ass'n*, 491 P.2d 1346 (Wash. Ct. App. 1971).

tation. It states a then-uncontroversial principle: "A duty of due, reasonable care binds [pesticide] manufacturers and sellers of products of this kind. This duty of care includes a duty to warn of product-connected dangers, a duty on the part of the manufacturer to subject the product to reasonable tests, and a duty on the part of the seller to subject the product to reasonable inspection." *Liability of Manufacturer or Seller for Injury Caused by Animal Feed or Medicines, Crop Sprays, Fertilizers, Insecticides, Rodenticides, and Similar Products*, 81 ALR 2d 138, 144 (1962).

2. *Before 1972, state and federal governments imposed extensive regulations on the content of pesticide labels*

At the same time that these common law damages actions challenging the validity of claims and warnings appearing on pesticide labels were widely proceeding, state and federal law imposed extensive pesticide labeling requirements. In 1910, Congress had enacted the Insecticide Act, ch. 191, 36 Stat. 331, repealed 61 Stat. 163, 172 (1947), which prohibited the sale of pesticides in interstate commerce if they bore labels containing false or misleading information. The 1947 Act, which repealed the Insecticide Act, imposed far more extensive federal labeling requirements. That statute declared a pesticide to be "misbranded" if its label included "any statement . . . which is false or misleading" or "if the label does not contain a warning or caution statement which may be necessary." 1947 Act § 2(z), *codified at* 7 U.S.C. § 135(z) (repealed).

Under the 1947 Act, the Department of Agriculture registered all pesticides moving in interstate commerce, and such registrations required federal approval of the language appearing on the pesticide label.[12] Department of Agriculture regulations required pesticide labels to contain certain features, including the name and address of the manufacturer, an

[12] 1947 Act § 4, *codified at* 7 U.S.C. § 135b (repealed).

ingredient statement, and certain caution or warning statements.[13] Federal regulations dictated the size, typeface, and position of the required label features.[14] Pesticides classified by the federal government as highly toxic were required to bear a label featuring the skull and crossbones symbol, the word "poison" in red lettering against a contrasting background, and emergency precautions.[15] Federal regulations established the language of specific warning statements for particular pesticides, such as benzene hexachloride and DDT.[16] As of November 1970, over 37,000 pesticide products had been registered pursuant to these regulations.[17]

At the same time, states had established extensive pesticide regulations; by 1972, all but two states had adopted pesticide registration laws.[18] State pesticide laws required registration of pesticides for use within the state. Although both the state and federal governments predicated registration on approval of pesticide labels pursuant to a set of regulatory labeling requirements, these requirements generally did not result in conflicting directives to pesticide companies because state agencies generally accepted the validity of federally registered labels.[19] This practice comported with federal policy

[13] 7 C.F.R. §§ 162.6, 162.7, 162.103 (1949).

[14] 7 C.F.R. §§ 162.102-105 (1949).

[15] 7 C.F.R. §§ 162.6, 162.9 (1949).

[16] 7 C.F.R. §§ 162.112, 162.114 (1949).

[17] *See* House Comm. Hearing at 96.

[18] See *id.* at 8, 21-22 (table of state pesticide laws).

[19] *See* Federal Environmental Pesticide Control Act: Hearings Before the Subcomm. on Ag. Research of the Sen. Comm. on Ag. and Forestry, 92d Cong., 1st Sess. (1971) ["1971 Senate Ag. Comm. Hearing"] at 489 (John H. Kirkpatrick, Director, Ag. Chem. Div., Alabama Dept. of Ag. and Industries) ("The State of Alabama registers pesticides without further investigation if a product has a USDA registration number."); Federal Environmental Pesticide Control Act: Hearings Before the Subcomm. on Ag. Research of the Sen. Comm. on Ag. and Forestry, 92d Cong., 2d Sess. (1972) ["1972 Senate Ag. Comm. Hearing"] at 155 (Charles H. Frommer, Director, Bureau of Pesticide Control, New York State Dept. of Env. Conservation); *but see* House Comm. Hearing at 829 (Errett Deck, Wash. Dept. of Ag.) ("Several states violate [the 1947 Act] by issuing state registrations for supplemental labeling for pesticides shipped into their state under a federally registered label.").

under the 1947 Act, in which Congress had considered it "highly desirable that the laws governing [pesticides] be as nearly uniform as possible . . . so that manufacturers may have Nation-wide distribution with a minimum of conflict between the labeling requirements of the various [state] laws."[20]

The state agencies imposed their own labeling requirements on products not covered by the 1947 Act, including pesticides formulated solely for intrastate use, which by 1972 were estimated to number as many as 25,000 products.[21] Some state agencies also registered federally-registered pesticides for uses not approved by the federal government and imposed labeling requirements on products registered under the 1947 Act.[22] In addition, many states' statutes authorized administrative agencies to regulate directly the uses of pesticides, not only their labeling.[23]

3. *At the time of the enactment of the 1972 Act, federal and state labeling requirements were not understood to preempt common law damages actions*

At the time Congress enacted the 1972 Act, the existence of extensive federal and state pesticide labeling requirements was not understood to affect the availability of common law

[20] H.R. Rep. No. 313, at 3 (1947), *reprinted in* 1947 U.S.C.C.A.N. 1202.

[21] *See* 1971 Sen. Ag. Comm. Hearing at 487, 489; Federal Environmental Pesticide Control Act of 1971: Hearings Before the Subcomm. on the Env't of the Sen. Comm. on Commerce, 92d Sess., 2d Sess. (1972) ["Sen. Commerce Comm. Hearing"] at 146.

[22] *See* 1972 Sen. Ag. Comm. Hearing at 341.

[23] *See* House Comm. Hearing at 21-22.

damages actions. Thus, in a wrongful death action against an insecticide manufacturer, the First Circuit concluded that federal approval of the product's label "merely satisfied" federal law but did not certify that the defendant had met the standard of due care imposed by state law.[24] Rather than supplanting state tort law, federal labeling requirements were widely understood to set minimum standards of care without otherwise altering state common law.[25]

Thus, by 1972, when section 136v(b) was enacted, it was widely recognized that pesticide manufacturers were liable both for personal injuries and crop damage resulting from pesticides, including for the failure to provide adequate warnings and instructions for the use of their products. Courts uniformly recognized that such common law actions did not conflict with extensive federal labeling requirements. As

[24] *Hubbard-Hall Chem. Co. v. Silverman*, 340 F.2d 402, 405 (1st Cir. 1965).

[25] *See, e.g., Griffin v. Planters Chem. Corp.*, 302 F. Supp. 937, 944 (D.S.C. 1969) ("Aside from the requirements set forth for the label by the Secretary of Agriculture, [defendants] had a duty to use a label, or furnish a warning commensurate with the danger."); *Gonzalez v. Virginia-Carolina Chem. Co.*, 239 F. Supp. 567, 572 (D.S.C. 1965) ("Even had the defendant not failed to warn the public as it was required to do by the Federal and State law, it is my opinion that the manufacturer of a hazardous material is under a common law duty to . . . give adequate warning."); *Mungy v. Magnolia Chem. Co.*, 437 S.W.2d 15, 19 (Tex. Ct. App. 1968) ("The statutes and regulations set minimum standards for those marketing economic poisons."); *Rumsey v. Freeway Manor Minimax*, 423 S.W.2d 387, 394 (Tex. Ct. App. 1968) (holding that 1972 Act does not "purport[] to change the common law duty to warn. . . . We are of the view that [the 1972 Act and its regulations] merely set minimum standards."); *Ebers v. General Chemical Co.*, 17 N.W.2d 176, 181 (Mich. 1945) ("Defendant cannot escape liability merely by showing that it followed the recommendations of the United States Department of Agriculture."); *McClanahan v. California Spray-Chem. Co.*, 75 S.E.2d 712 (Va. 1953) (violation of 1972 Act constitutes negligence per se in state tort action); *Perry Creek Cranberry Corp. v. Hopkins Ag. Chem. Co.*, 139 N.W.2d 96, 102 (Wisc. 1966) (same).

discussed in the next section, Congress had no intent to alter this settled body of law when it enacted Section 136v(b).

B. The Legislative History of the 1972 Act Demonstrates that Section 136v(b) Is Directed Solely at the Continued Regulatory Authority of State Agencies in Light of the Expansion of Federal Power

The legislative history of the 1972 Act demonstrates that Congress gave no consideration to preempting any aspect of state tort law and had no intent to eliminate any common law damages remedies. The 1972 Act is not one whose legislative history is scanty, confused, or ambiguous. On the contrary, the legislative history of 1972 Act is voluminous and, on this point, very clear. In 1971 and 1972, three House and Senate committees held 25 days of hearings on proposed pesticide legislation, the transcripts of which fill over 2300 pages.[26] Each committee issued a report, filling over 275 pages.[27] A conference committee issued a 34-page report.[28] Floor debates occurred over five days, the transcripts of which fill over 150 pages in the Congressional Record.[29] What became

[26] *See* House Comm. Hearing; 1971 Senate Ag. Comm. Hearing; 1972 Senate Ag. Comm. Hearing; Sen. Commerce Comm. Hearing.

[27] *See* H.R. Rep. No. 511, 92d Cong., 1st Sess. (1971) ["House Comm. Report"]; Sen. Ag. Comm. Report; S. Rep. No. 838 (Supplemental Report), 92d Cong., 2d Sess. (1972) ["Supplemental Sen. Ag. Comm. Report"]; S. Rep. No. 970, 92d Cong., 2d Sess. (1972) ["Sen. Commerce Comm. Report"].

[28] H.R. Conf. Rep. No. 1540, 92d Cong., 2d Sess. (1972) ["Conf. Comm. Report"].

[29] 117 Cong. Rec. H10674-H10680 (Daily Edition, Nov. 8, 1971) (House debate); 117 Cong. Rec. H10726-10774 (Daily Edition, Nov. 9, 1971) (House debate and passage); 118 Cong. Rec. S15885-S15900 (Daily Edition, Sept. 26, 1972) (Sen. debate and passage); 118 Cong. Rec. S16977-S16981 (Daily Edition, Oct. 5, 1972) (Sen. debate and passage of conference report); 118 Cong. Rec. H9795-H9798 (Daily Edition, Oct. 12, 1972).

Section 136v was debated at considerable length. But, in those thousands of pages of hearings, reports, and transcripts of floor debates, there is precisely *no* mention of any concern about the availability of state tort law—and no discussion of the preemption of any aspect of state tort law.

1. *The legislative history of the 1972 Act is devoid of any suggestion of an intent to preempt common law damages actions*

EPA General Counsel John Quarles, appearing as the first witness in the first committee hearing on the Administration's proposed pesticide bill, stated unequivocally: "The bill does not affect tort liability."[30] No witness appearing thereafter, nor any Member of Congress, suggested otherwise. While the legislative history includes several other scattered references to the availability of common law damages actions, none suggest any intent to preempt such actions.[31]

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[30] House Comm. Hearing at 42. The statement came in response to a question from Rep. Foley, who asked Mr. Quarles whether application of pesticides in compliance with EPA regulations would "grant complete immunity" to the applicator and establish "prima facie evidence of complete compliance with the law." Rep. W.R. Poage, Chairman of the House Agriculture Committee, interrupted to ask whether Rep. Foley was suggesting that the bill would immunize users of pesticides from common law damages actions: "Surely, you do not mean to say that if I have a mesquite pasture here, and Mr. Stubblefield had a field of cotton adjoining it, and I sprayed 2,4,5-T on my mesquite pasture, and it goes over on his property, he would not have a cause of action against me?" After Mr. Quarles gave the answer quoted above, Rep. Foley clarified that his question was directed at immunity from statutory penalties, not common law damages.

[31] For instance, the Senate Commerce Committee Report includes a letter from Professor John J. Flynn, who stated that federal pesticide law should "insure to a limited degree that the product will perform its function without substantial adverse effects on the environment" even though "the common law of negligence and warranty already imposes such a burden upon the manufacture of a product." Sen. Commerce Comm. Report at 18. A witness for Hercules, Inc., a pesticide manufacturer, acknowledged that his company had been sued for products liability, and a witness for a pest control trade association likewise acknowledged liability suits, adding that they had "never been a problem that was serious enough for us to consider it a difficulty." House Comm. Hearing at 415; 1971 Sen. Ag. Comm. Hearing at 467. An entomologist mentioned that he had appeared as an expert witness in two cases brought by farmers against pesticide manufacturers. 1971 Sen. Ag. Comm. Hearing at 612. A witness for migrant farm workers, advocating that EPA require that pesticide labels include warnings on how long laborers should avoid fields after pesticide application, suggested that such a labeling requirement might "facilitate the conduct of law suits" by providing "some evidence of what the standard of care is." 1972 Sen. Ag. Comm. Hearing at 314.

Over the course of the hearings, thirty-three witnesses testified on behalf of the pesticide industry, and not one suggested that the availability of common law damages actions undermined their ability to produce uniform labels, and none of these industry witnesses asked for federal protection from common law damages actions.[32] The industry

Debate over the 1972 Act's indemnification provision, enacted as 7 U.S.C. § 136m, suggests that Congress anticipated that state damages actions would remain available to provide redress for harms caused by pesticides. Section 136m requires that, under certain circumstances when EPA cancels a pesticide registration and thereby removes it from the market, the government must make an indemnity payment to those in possession of the now unusable and worthless pesticide. In the Senate Commerce Committee Hearing, Senator Curtis asked whether the provision was intended to indemnify pesticide manufacturers "in case of injury to an individual's health or life," but David D. Dominick, EPA Assistant Administrator, explained that "[t]he indemnities do not go to liability for tort or other public problems of that sort." 1972 Sen. Ag. Comm. Hearing 93. On the House Floor, a similar question was raised as to whether the indemnity provision was intended to provide compensation for persons injured by pesticides; Representative Teague explained that it "has nothing to do with losses they might have suffered because of any damage done by pesticides." 117 Cong. Rec. H10758 (Daily Edition, Nov. 9, 1971).

[32] *See* House Comm. Hearing at 279-287 (Robert L. Ackerly, Chemical Specialties Manuf's Assn., Inc.); *id.* at 288-316 (R.E. Naegele and Donald

witnesses expressed various concerns about federal regulation of pesticides and the proposed new pesticide law, including reservations about the increased regulatory power of EPA and fear that EPA might cancel pesticides' registrations without taking sufficient account of the chemicals' benefits or the scientific evidence.[33] Industry witnesses also expressed concerns about the costs imposed on pesticide manufactures by federal regulation.[34] But the concerns raised by the industry

D. McCollister, Dow Chemical Co.); *id.* at 316-322 (William Brehm and C.P. Stephenson, United Pesticides Formulation and Dist'rs Assn.); *id.* at 322-328 (Wayne F. Gustafson, Gustafson Manufacturing, Inc.); *id.* at 329-333 (Richard H. Wellman, Union Carbide Corp.); *id.* at 333-369 (Parke C. Brinkley and John D. Conner, Nat'l Ag. Chems. Assn.; John J. Hood, Dr. C. Boyd Shaffer, and Dr. Frank L. Lyman, Ciba-Geigy Corp.); *id.* at 369-370 (Lewis E. Goyette, Southeastern Ag. Chems. Assn.); *id.* at 370-375 (H.L. Straube, Iver C. MacDougall, and A.B. Linquist, Stauffer Chem. Co.); *id.* at 377-383 (K.R. Fitzsimmons and Dr. M.J. Sloan, Shell Chem. Co.); *id.* at 383-394 (J.G. Copeland, Dr. John P. Frawley, John G. Kuniholm, Charles L. Dunn, and Kenneth T. Givens, Hercules, Inc.); *id.* at 394-398 (Richard A. McDonald, Paper Products, Inc.); *id.* at 398-417 (Dr. Donald A. Spencer, Ciba-Geigy Corp.); 1971 Sen. Ag. Comm. Hearing at 411-415 (Carlos Kampeier, Nat'l Ag. Chems. Assn.); *id.* at 415-421 (Parke C. Brinkley, Nat'l Ag. Chems. Assn.); *id.* at 421-460 (John D. Conner, Nat'l Ag. Chems. Assn.); *id.* at 461-468 (William L. Brehm, United Pesticide Formulators & Dist'rs Assn.); *id.* at 468-469 (Roland L. Rhodes, United Pesticide Formulators & Dist'rs Assn.); *id.* at 469-473 (C.P. Stephenson, United Pesticide Formulators & Dist'rs Assn.); *id.* at 508-513 (Arthur B. Chivvis, Chem. Specialties Manuf'rs Assn.); *id.* at 536-548 (J.G. Copeland, Jr., Hercules, Inc.); 1972 Sen. Ag. Comm. Hearing at 239-259 (Edward K. Hertel, Nat'l Ag. Chems. Assn.); *id.* at 259-261 (Parke C. Brinkley, Nat'l Ag. Chems. Assn.); *id.* at 262-268 (Carlos Kampmeier, Nat'l Ag. Chems. Assn.); Sen. Commerce Comm. Hearing at 133-156 (David Phillipson and John D. Conner, Nat'l Ag. Chems. Assn; John J. Hood, Ciba-Geigy Corp.; Dr. C. Boyd Shaffer, American Cyanamid Co.; Dr. John S. Tobin, Niagara Chem. Div.; and Dr. Ronald Spencer, Nat'l Ag. Chems. Assn.).

[33] *See, e.g.*, House Comm. Hearing at 280-281, 288-302, 331, 407, 439, 814.

included no objection to the continued availability of common law damages actions.

Thirty witnesses testified on behalf of federal regulatory authorities, but not one suggested that the availability of state common law damages actions, including actions challenging the adequacy of federally approved labels, created any conflict with federal regulations or posed any obstacle to the effective administration of federal labeling regulations.[35]

[34] *See, e.g., id.* at 302, 332, 349; 1971 Sen. Ag. Comm Hearing at 413; 1972 Sen. Ag. Comm. Hearing at 257. To address this concern, the pesticide industry successfully sought indemnification from the federal government to pay pesticide manufacturers, dealers, and consumers the market rate of any pesticides they held at the time of suspension or cancellation. *See* 7 U.S.C. § 136m.

[35] *See* House Comm. Hearing at 33-52 (John Quarles, Ray Johnson, and Lowell E. Miller, EPA); *id.* at 53-88 (J. Phil Campbell, Dr. Francis J. Mulhern, Dr. H.C. Cox, Dr. Velmar W. Davis, Arthur W. Greely, Lotus Therkelsen Prokop, Dr. Fred H. Tschirely, Turner Oyloe, and Dr. Ned Bayley, U.S. Dept. of Ag.); *id.* at 89-111 (Dr. Albert C. Kolbye, Lessell L. Ramsey, and Reo Duggan, FDA); *id.* at 111-120 (Harrison Loesch and Paul E. Thompson, U.S. Dept. of the Interior); *id.* at 120-135 (Edwin M. Cronk and Joseph E. O'Mahony, U.S. Dept. of State); *id.* at 137-148 (Dr. E.F. Knipling, U.S. Dept. of Ag.); *id.* at 152-164 (David E. Ketcham, U.S. Dept. of Ag.); *id.* at 169-180 (W.B. Ennis, Jr., U.S. Dept. of Ag.); *id.* at 180-188 (W.D. McClellan, U.S. Dept. of Ag.); *id.* at 707-728 (Russell Train, President's Council on Environmental Quality); *id.* at 728-751 (William D. Ruckelshaus, EPA); 1971 Sen. Ag. Comm. Hearing at 160-191 (Russell E. Train, President's Council on Environmental Quality); *id.* at 191-203 (Dr. Ned D. Bayley, U.S. Dept. of Ag.); *id.* at 203-206 (Lotus Prokop, U.S. Dept. of Ag.); *id.* at 206 (Dr. Francis Mulhern, U.S. Dept. of Ag.); *id.* (Dr. T.C. Byerly, U.S. Dept. of Ag.); *id.* at 207-211 (Fred H. Tscherley, U.S. Dept. of Ag.); *id.* at 290-302 (William D. Ruckelshaus, EPA); *id.* at 302-307 (Dr. Raymond Johnson, EPA); *id.* at 307-325 (John R. Quarles, EPA); 1972 Sen. Ag. Comm. Hearing at 80-98 (David D. Dominick, EPA); *id.* at 98-111 (Dr. William M. Upholt, EPA); *id.* at 111-114 (T.C. Byerly, U.S. Dept. of Ag.); *id.* at 114-116 (Harold Carter, U.S. Dept. of Ag.); Sen. Commerce Comm. Hearing at 156-170 (David D. Dominick, Dr. William M. Upholt, and Charles Fabrikant, EPA).

Thirty-eight witnesses also testified on behalf of pesticide users, including representatives of farmers, exterminators, and homemakers.[36] These witnesses generally were concerned that Congress might overly restrict the availability of pesticides, but none of them expressed any concern that the proposed law might eliminate their existing right to obtain compensation in the event they suffered personal or economic injury resulting from pesticide manufacturers; false claims, ineffective products, or inadequate warnings.

[36] *See* House Comm. Hearing at 419-424 (Ralph E. Neal, National Pest Control Assn.); *id.* at 424-427 (Robert Russell, Orkin Exterminating Co.); *id.* at 427-432 (James W. Streckel, National Pest Control Assn.); *id.* at 433-441 (Lon Mann, Bruce Lynn, and Dr. James Brown, National Cotton Council); *id.* at 457-478 (Clifford G. McIntire, Boswell Stevens, and Richard McGuire, American Farm Bureau); *id.* at 483-488 (Don F. Magdanz and Oscar Breedthauer, National Livestock Feeders Assn.); *id.* at 488-491 (Robert J. Sullivan, Christmas Tree Growers Assn.); *id.* at 491-496 (Robert E. Lee III, American Pulpwood Assn.); *id.* at 496-520 (William H. Lawrence and John F. Hall, National Forest Products Assn.); *id.* at 521-526 (L.C. "Clell" Carpenter and Stuart Spradling, Mid-Continent Farmers Assn.); *id.* at 526-530 (Henry M. Tobey and Charles Hromada, Cook Indus., Inc.); *id.* at 530-534 (Betty Chapman, "Housewife"); *id.* at 540-543 (Richard T. O'Connell, National Council of Farmer Cooperatives); *id.* at 543-555 (Reuben Johnson, National Farmers Union); *id.* at 558-562 (John Matthews and C.W. McMillan, American National Cattlemen's Assn.); *id.* at 566-575 (John W. Scott and Robert M. Frederick, National Grange); *id.* at 590-594 (Bailey Sanistevan and Virgil Mowry, California Fieldmen's Assn.); *id.* at 594-609 (Harry L. Graham, National Farmers Org.); 1971 Sen. Ag. Comm. Hearing at 211-223 (Lon Mann, National Cotton Council of America); *id.* at 223-253 (Dr. James M. Brown, National Cotton Council of America); *id.* at 253-262 (L.C. "Clell" Carpenter and Stuart Spradling, Missouri Farmers Assn.); *id.* at 262-273 (John W. Scott and Robert M. Frederick, National Grange); *id.* at 273-277 (Harry L. Graham, Nat'l Farmers Org.); *id.* at 346-351 (Clifford G. McIntyre, American Farm Bureau); *id.* at 351-358 (J.D. Hays, American Farm Bureau Fed'n); *id.* at 389-395 (Robert E. Lee III, American Pulpwood Assn.); *id.* at 395-403 (J. Edwin Moore, American Pulpwood Assn.); *id.* at 499-508 (Dr. Ralph E. Heal, National Pest Control Assn.); *id.* at 603-608 (Robert M. Russell and Dr. Michael Shinkle, Orkin Exterm'g Co.); *id.* at 699-703 (Henry M. Tobey, Cook Indus.); 1972 Sen. Ag. Comm. Hearing at 233-239 (Reuben L. Johnson, Nat'l Farmers Union); *id.* at 285-289 (Dr. Ralph E. Heal, Nat'l Pest Control Ass'n); *id.* at 289-293 (L.C. Carpenter and Stuart Spradling, Missouri Farmers Assn.); *id.* at 299-300 (Robert M. Russell, Orkin Exterm'g Co.); *id.* at 305-314 (Kevin Carey, Migrant Legal Action Program); *id.* at 317-348 (A.V. Krebs, Agribusiness Accountability Project); *id.* at 348-354 (Jeffrey Liddle, Orange County Legal Svcs. Project); *id.* at 354-362 (Anita Johnson, Public Interest Res. Gp.); Sen. Commerce Comm. Hearing at 78-90 (A.V. Krebs, Valerie Kantor, and Jerry Berman, Migrant Legal Action).

In the committee reports, floor debates, and conference committee report on the 1972 Act, Congress carefully and repeatedly described the changes it intended to make through the Act.[37] No mention was made that the Act would eliminate any of the common law remedies long and widely available to persons injured by pesticides. The absence of any discussion of eliminating common law damages actions contrasts sharply with the voluminous testimony Congress heard regarding the harms to human health posed by pesticides.[38]

[37] *See* House Comm. Report at 1-2, 12-13; Sen. Ag. Comm. Report at 1-2, 4-6; Sen. Commerce Comm. Report at 8; 118 Cong. Rec. S15889 (Daily Edition, Sept. 26, 1972); *id.* at S15893-15894 (Sen. Allen); 118 Cong. Rec. H9795 (Daily Edition, Oct. 12, 1972).

[38] *See, e.g.,* Sen. Commerce Comm. Report at 27 ("[A]s many as 800 workers are killed each year and over 800,000 injured as a result of the unwise and improper use of pesticides"); House Comm. Report at 71 (additional views of Rep. John Dow) (citing reports that 50,000 people in U.S. are poisoned by pesticides annually); House Comm. Hearing at 111-120 (Harrison Loesch, Assistant Secretary of the Interior); *Id.* at 138 (Dr. E.F. Knipling, Science Adviser to U.S.D.A.); *Id.* at 708 (Russell Train, Chairman, President's Council on Environmental Quality); 1971 Sen. Ag. Comm. Hearing at 539 (J.G. Copeland, Hercules, Inc.); *id.* at 791 (Charles M. Creuziger, Veg. Growers Assn. of America); 1972 Sen. Ag. Comm. Hearing at 98 (Dr. William M. Upholt, Deputy Assistant Administrator for Pesticide Programs, EPA); *id.* at 310 (Max B. Rothman, Farm Worker Div., Camden Regional Legal Services); *id.* at 318 (A.V. Krebs, Agribusiness Accountability Project).

What a plurality of this Court said in *Medtronic* with regard to the Medical Devices Amendments of 1976 applies equally to the 1972 Act: "There is, to the best of our knowledge, nothing in the hearings, the committee reports, or the debates suggesting that any proponent of the legislation intended a sweeping pre-emption of traditional common law remedies . . . If Congress intended such a result, its failure even to hint at it is spectacularly odd." 518 U.S. at 491. Had Congress intended to deprive persons injured by mislabeled pesticides of the right to compensation for their injuries, one would expect Congress to have mentioned this intent somewhere in the many thousands of pages of legislative history. It did not.

On the contrary, the 1972 Act was enacted in large part to provide increased protection against these harms.[39] Preemption of state damages actions would thus "have the perverse effect of granting complete immunity . . . to an industry that, in the judgment of Congress, needed more stringent regulation." *Medtronic*, 518 U.S. at 487 (plurality opinion).

2. *The legislative history confirms that Section 136v was directed solely at the continuing regulatory authority of state administrative agencies*

The legislative history of the 1972 Act makes clear that Section 136v was directed at a concern entirely unrelated to the availability of state tort damages. The provision seeks to delineate the authority of state agencies to regulate pesticides. While the availability of common law damages actions was never discussed or debated over the course of the history of the 1972 Act, the issue of the continuing regulatory authority of state administrative agencies was a subject of voluminous hearing testimony, was discussed in every committee report,

[39] Sen. Ag. Comm. Report at 3 (stating the 1972 Act provides increased "protection of man and his environment").

and was debated at length on the floor of both the House and Senate.[40]

The changes in pesticide regulation proposed for (and, to a substantial, but lesser extent, effected by) the 1972 legislation necessitated extensive consideration of the state administrators' regulatory because the Act extended federal authority into two subject matter areas that previously had been regulated exclusively by the states: direct regulation of pesticide use and registration of pesticides formulated for intrastate use.[41]

[40] *See, e.g.,* House Comm. Hearing at 478-483 (Charles P. Ellington, Stanwood Cath, Dr. Vincent Stewart, and Jonn Hillis, National Assn. of State Depts. of Ag.); 1971 Sen. Ag. Comm. Hearing at 325-346 (Charles P. Ellington, National Assn. of State Depts. of Ag.); *id.* at 486-491 (W.A. Ruffin, Ala. Dept. of Ag. and Indus.); *id.* at 491-496 (John H. Kirkpatrick, Ala. Dept. of Ag. and Indus.); *id.* at 496-499 (J.R. Conley, Ga. Dept. of Ag.); 1972 Sen. Ag. Comm. Hearing at 116-123 (Dr. Donald R. Isleib, Mich. Dept. of Ag.); *id.* at 151-156 (Charles H. Frommer, New York Dept. of Environmental Conservation); *id.* at 268-285 (Errett Deck, Assn. of American Pesticide Control Officials); House Comm. Report at 1-2, 16; Sen. Ag. Comm. Report at 16-17, 30; Sen. Commerce Comm. Report at 7, 44; Supplemental Sen. Ag. Comm. Report at 51-57; Conf. Comm. Report at 33; 117 Cong. Rec. H10740-H10744, H10751 (Daily Edition, Nov. 9, 1971); 118 Cong. Rec. S15888-S15889, S15893-S15894 (Daily Edition, Sept. 26, 1972); 118 Cong. Rec. H9184 (Daily Edition, Oct. 5, 1972); 118 Cong. Rec. 16978 (Daily Edition, Oct. 5, 1972).

[41] *See* Sen. Ag. Comm. Report at 1 ("The new bill would (A) regulate the use of pesticides to protect man and his environment; and (B) extend Federal pesticide regulation to actions entirely within a single State."); *see also* Statement by the President Upon Signing the Bill Into Law (Oct. 21, 1972) (declaring that the 1947 Act did "not address the problem of misusing properly registered pesticides and it did not control pesticides which moved solely in intrastate commerce. The new law remedies these defects."); 118 Cong. Rec. S15893 (Daily Edition Sept. 26, 1972) (Sen. Allen) ("[T]his bill does two things. First, it provides for regulating the use of pesticides, as distinguished from their labeling and interstate distribution. Second, it extends pesticide regulation to intrastate commerce.").

a. The committee hearings. The original pesticide bill sponsored by the Nixon Administration and introduced in the House by Representative W.R. Poage, Chairman of the House Agriculture Committee, did not directly address the authority of state agencies to continue their programs of pesticide registration and regulation.[42] Testifying on behalf of the Administration, EPA General Counsel John Quarles emphasized that the bill was intended to maintain state agencies' authority to regulate pesticide use more stringently than did the federal government: "States thus are not precluded from imposing stricter standards or added requirements."[43]

Notwithstanding the Administration's indicated intent, witnesses for the states were greatly troubled by the absence of a provision expressly affirming that their regulatory authority was undiminished. The representative of the National Association of State Departments of Agriculture testified that: "It is our feeling that it will be better for Congress to clearly indicate its intentions in this bill rather than leaving this area a glaring omission and have a battery of fellow lawyers and courts trying to answer these questions later on."[44] Witnesses for the state agencies feared that the bill could be construed to completely oust them of their existing authority.[45] The state

[42] *See* H.R. 4152, 92d Cong., 1st Sess. (introduced Feb. 10, 1971), *reprinted in* House Comm. Hearing at 859-904.

[43] House Comm. Hearing at 8.

[44] 1971 Sen. Ag. Comm. Hearing at 338.

[45] *See, e.g.,* House Comm. Hearing at 851 (H.L. Bruer, Tenn. Dept. of Ag.) ("We find several objectionable features in this Bill, one of them being that the Bill, as now drawn, pre-empts all authority for the registration and regulation of sale and use of pesticides."); 1971 Sen. Ag. Comm. Hearing at 336 (Dr. Charles P. Ellington, National Assn. of State Depts. of Ag.) ("The bill before you would completely preempt State registration and if enacted and enforced as written there would no longer be any need for State registration laws."); *id.* at 339 ("We are concerned however, Mr. Chairman, over the bill as it is written now completely preempting State programs that are in effect today."); 1971 Sen. Ag. Comm. Hearing at 745 (Dave L. Pearce, Commissioner, Louisiana Dept. of Ag.) ("Perhaps the worst feature of the proposed Act is that it takes pesticide regulation from state control.").

agencies expressed concern about the loss of jobs and funding that might result if their functions were taken over by EPA.[46] The states were also concerned about the potential preemption of their authority to regulate the uses of pesticides, to register pesticides for local uses not approved by the federal government, and to register "intrastate" pesticides.[47] The state

[46] *See* House Comm. Hearing at 479-480 (Charles P. Ellington, Director, Maryland Board of Ag., on behalf of Nat'l Ass'n of State Depts. of Ag.) ("[T]here are 250 people experienced in pesticide registration and inspection that are on the job today in the States. The bill before you would completely preempt States in this field if enacted and enforced as written."); *id.* at 513-514 (Dr. Vincent E. Stewart, Florida Dept. of Ag.) ("We have 25 laboratory personnel who are involved in chemical examination of pesticides and pesticide residues. We have 13 . . . full-time pesticide inspectors. . . . [I]f this bill . . . passes, this will eliminate the registration of pesticides in our State."); *id.* at 517 (Dr. Ellington) ("[T]here would no longer be any need for us to be in the registration business, we would simply get out of it. . . . I can almost predict with certainty that in a matter of a few years, there will be no State registration programs at all unless there is this cooperative program or joint program that I mentioned. And the bill is not specific in this regard."); 1971 Sen. Ag. Comm. Hearing at 336 (Ellington).

[47] House Comm. Hearing at 829 (Errett Deck, Wash. Dept. of Ag.) ("There is no provision for state registered uses which deviate in any way from the labeling of a pesticide registered for interstate shipment."); *id.* at 851 (H.L. Bruer, Tenn. Dept. of Ag.) ("The Bill would make it impossible for a State to register a pesticide material for a purely local need and use."); *id.* at 857 (James A. Graham, NC Dept. of Ag.) ("The proposed Law does not provide for state registered uses which deviate from the labeling of a federally registered pesticide. . . . I agree with the idea that uniform labeling of pesticides across the country should be promoted as is encouraged by the Law when feasible. However, the single label concept cannot provide for the proper use of pesticides in all areas of the country. Each state must be allowed to further restrict uses of certain pesticides due to unique situations or environmental problems that may arise."); 1971 Sen. Ag. Comm. Hearing at 497 (J.R. Conley, Ga. Dept. of Ag.) ("We do not wish to imply that we are opposed to regulations at the Federal level

agencies proposed that the Administration's bill be amended to clarify that the states maintained their existing regulatory authority in these areas.[48]

Witnesses for the pesticide industry were also concerned about the absence of a provision delineating state regulatory authority. These witnesses were concerned that, if the states were allowed to maintain their existing authority to register pesticides and thereby regulate the content of pesticide labels, different state agencies might impose conflicting label requirements, making it impossible for manufacturers to produce a pesticide with a single label for national marketing. As the general counsel for the Chemical Specialties Manufacturers Association testified:

> [The proposed bill] invites a multiplicity of requirements. Some States might want the word "flammable," some "inflammable." . . . Some States might want red lettering; others orange, another yellow, and so forth. We ask this committee, therefore, to recognize, as the Congress has in a number of similar statutes, the

as is borne out by our current cooperative efforts, but we do with to emphasize that we, like all the other States, have regional and local problems which sometimes require immediate, severe, and unconventional means of attack."); *id.* at 498 ("Provision is made that no product which is not federally registered could be sold within a State, and with Federal registration procedures what they are today, the State departments of agriculture and other agencies would be helpless to provide assistance in times of local crises."); *id.* at 486 (W.A. Ruffin, Alabama Dept. of Ag. and Industries) ("We oppose this bill because it abrogates State authority and responsibility to regulate pesticide products intrastate. . . . Local problems are best handled by knowledgeable personnel either responsible to or working in State government who are aware of local needs.").

[48] *See* House Comm. Hearing at 829 (Errett Deck, Wash. Dept. of Ag.); *see also id.* at 796 (proposal of American Frozen Food Institute to allow states to approve supplemental label for uses allowed in their states); 1971 Sen. Ag. Comm. Hearing at 754 (same).

> industry's need for uniformity by providing for this in the act.[49]

As the witness explained, uniformity of labeling requirements was important because of the expense of producing pesticide packaging for national marketing.[50] As another industry witness explained, "If each state were free to impose labeling, packaging, or other restrictions on the manufacturer, such regulatory procedures would become unworkable for responsible national firms."[51] The president of the National Agricultural Chemicals Association asserted that, with federal registration of all pesticides, including intrastate pesticides, "there would be no need or room for conflicting State or local regulations."[52]

Witnesses for the state pesticide-regulating agencies took differing positions on federal preemption of state authority to impose labeling requirements. On one hand, a witness for the New York agency responsible for regulating pesticides indicated support for a general prohibition on state-imposed labeling requirements, declaring that "[i]t makes it a lot easier for the manufacturer to put on one label rather than 50 labels, plus possibly a label for each of the territories."[53] On the other hand, witnesses representing other state agencies opposed such a prohibition on the ground that it precluded the states from developing labeling regulations that were stricter

[49] House Comm. Hearing at 281-283 (Robert L. Ackerly).

[50] *Id.*; *see also* 1971 Sen. Ag. Comm. Hearing at 508 (Arthur B. Chivvis, President, Chemical Specialties Manufacturers Assn.) ("To invite States to ignore the Federal registration and impose their own separate requirements on the label would create a nightmare. The distribution practices of the industry preclude marketing one product in Maryland, one in New York, *et cetera*.").

[51] *Id.* at 802 (A.M. McVie, President of Elanco Products, Inc.).

[52] 1971 Sen. Ag. Comm. Hearing at 418.

[53] 1972 Sen. Ag. Comm. Hearing at 153 (Charles Frommer, Dir., Bur. of Pesticide Control, NY State Dept. of Env. Conservation).

than those of the federal government.[54] Environmental groups too supported the authority of state agencies to impose labeling requirements stricter than those imposed by EPA.[55]

b. The development of Section 136v in the House and Senate. To address the various concerns over the authority of the state regulatory bodies raised by both the state agencies and the pesticide industry, the House Agriculture Committee amended the administration's bill to add Section 24, a provision expressly addressing the authority of the state agencies. As passed by the Committee, Section 24 had three subsections, which—after several significant changes—were enacted into law and codified in Section 136v. In the House Committee's original version, subsection (a) would have allowed the states to regulate the use of only one class of pesticides ("restricted use" pesticides) more strictly than the federal government, as long as the states did not require permits or licenses to use such pesticides; subsection (b) would have prohibited the states from imposing or continuing in effect any labeling requirements different from those

[54] *Id.* at 275 (Errett Deck, Wash. Dept. of Ag., on behalf of National Assn. of State Depts. of Ag. and the Assn of Am. Pesticide Control Officials) ("[S]tates which now require a quantitative percentage active ingredient statement will be forced to accept labeling without the percentage of each active ingredient because of the labeling pre-exemption [sic] provision of Sec. 24(b)."); *id.* at 374 (Irwin Mann, Jr., Director, Oregon Dept. of Ag.); *id.* at 376 (Clinton E. Jeffers, Commissioner, Colorado Dept. of Ag.) ("HR 10729 as introduced into the Senate . . . does permit the States to restrict the uses of any pesticides under the authority of Section 24(a), but subparagraph (b) of this section negates such authority.");1972 Sen. Ag. Comm. Hearing at 374 (Irwin Mann, Jr., director Oregon Dept. of Ag.) ("We, therefore, urge that you give consideration to amending Section 24(c) of HR 10729 to permit states to determine their need for pest control, to determine directions for use, and to register all pesticides distributed and used within their boundaries."); *id.* at 376 (Clinton E. Jeffers, Comm'r, Colo. Dept. of Ag.).

[55] *Id.* at 137 (Sierra Club proposal); *id.* at 168 (William A. Butler, Environmental Defense Fund).

imposed by the EPA; and subsection (c) would have left state regulators with a very limited role in the registration of intrastate pesticides, allowing them to "assist" EPA in registering pesticides for intrastate distribution but otherwise preempting them from imposing any requirements on the labels for intrastate pesticides.[56]

In the debates on the House Floor, many House Members opposed the proposed subsection (a) because it limited state authority to establish stricter regulations on the use of pesticides. As these opponents explained, precluding the states from controlling pesticide uses "would gut the laws of such States where such laws are stricter than the Federal regulation."[57] In response, Representative Kyl introduced an amendment to subsection (a), which was adopted by the House and subsequently enacted into law, protecting the authority of state regulators to impose limitations on pesticide use more stringent than those imposed by EPA.[58]

Meanwhile, subsection (c) was revised by the Senate Agriculture and Forestry Committee to reaffirm states' authority to register pesticides for local uses. Although the state agency witnesses had generally accepted the proposition that labeling requirements should be uniform in order to allow pesticide manufacturers to market their products

[56] H.R. 10729 § 24 (Sept. 16, 1971), *reprinted in* 117 Cong. Rec. H10733 (Daily Edition, Nov. 9, 1971).

[57] 117 Cong. Rec. H10740 (Daily Edition, Nov. 9, 1971) (Rep. Dow); *see also id.* (Rep. Helstoski) ("The preemption of State authority in section 24 seems clearly aimed at the heart of these strong State programs."); *id.* at H10741 (quoting letter from Henry L. Diamond, Commissioner, New York Dept. of Env. Conservation); *id.* (quoting letter from Richard J. Sullivan, Commissioner, New Jersey Dept. of Env. Protection); *id.* (quoting telegram from Daniel W. Lufkin, Conn. Comm. of Env. Protection); *id.* at H10742 (Rep. Harrington); *id.* at H10743 (Rep. Abzug); *id.* at H10743 (Rep. Anderson); *id.* at H10744 (Rep. Wolff).

[58] *Id.* at H10751.

nationally,[59] they fought to maintain their authority to register pesticides for local uses additional to those approved by the federal government—and thereby to regulate the content of supplemental labels for use only in their individual states.[60] As passed by the Senate, and subsequently enacted into law, subsection (c) preserves state regulators' authority to register pesticides formulated for in-state use.[61]

c. Discussion of Section 136v in the House and Senate Committee Reports. The four House and Senate committee reports describe in considerable detail the changes in pesticide regulation Congress intended to accomplish through the 1972 Act. The reports agree that "[t]he thrust of these amendments is to change FIFRA from a labeling law into a comprehensive regulatory statute that will henceforth more carefully control the manufacture, distribution, and use of pesticides."[62] The reports discuss state agencies' continuing authority to regulate pesticide use and emphasize that the bill

[59] *See, e.g.*, House Comm. Hearing at 834 (Maurice B. Rowe, Commissioner of Virginia Dept. of Ag.) ("[W]e can understand why manufacturers, most of whom are distributing their products in many states, need uniformity in labeling requirements."); *id.* at 835 (recognizing that national registration of pesticides would "lessen the problem of manufacturers developing special labels for individual state requirements"); 1971 Sen. Ag. Comm. Hearing at 346 (Dr. Charles P. Ellington, National Assn. of State Depts. of Ag.).

[60] *See* 1972 Sen. Ag. Comm. Hearing at 153-155 (Charles H. Frommer, New York Bureau of Pesticide Control); *id.* at 269 (Errett Deck, Wash. Dept. of Ag., on behalf of National Assn. of State Depts. of Ag. and the Assn of Am. Pesticide Control Officials), *id.* at 371 (James A. McHale, Penn. Sec. of Ag.); *id.* at 374 (Irwin Mann, Jr., director Oregon Dept. of Ag.) *id.* at 376 (Clinton E. Jeffers, Commissioner, Colorado Dept. of Ag.).

[61] H.R. 10729 § 23(c) (July 19, 1972), *reprinted in* Sen. Ag. Comm. Report at 71; *see* Conf. Comm. Report at 33 (subsection (c) "[m]akes it clear that a state may provide registration to meet special local needs (subject to disapproval by the Administrator)").

[62] House Comm. Report at 1; *see also* Sen. Ag. Comm. Report at 1-2; Sen. Commerce Comm. Report at 8.

was intended to establish a "coordinated Federal-State administrative system to carry out the new program."[63]

The reports explain the changes in pesticide regulation intended to be accomplished through the 1972 Act, and offer detailed comparisons between old and new laws—without any mention of any effect the 1972 Act would have on state common law damages actions.[64] Each of the two Senate reports contains the same, single sentence addressing the limitation on state authority to impose labeling requirements: "Subsection (b) preempts any State labeling or packaging requirements differing from such requirements under the Act."[65] If Congress intended subsection (b) to eliminate the longstanding right of persons injured by mislabeled pesticides to receive compensation, it expressed this intention in astonishingly oblique language.

The House Committee Report uses somewhat different language, declaring that the bill "is intended to completely preempt State authority in regard to labeling and packaging."[66] In their Brief in Opposition submitted to this Court, Respondents relied on this language to support their assertion that Congress intended to preempt any common law damages actions that challenge the adequacy of warnings, instructions, or claims made on pesticide labels.[67] But, whatever the House Agriculture Committee may have meant in expressing an intent to "completely" preempt state labeling authority, this intent was not actually carried out in the 1972 Act. As the committee report states, a key aspect of the intent to "completely" preempt state labeling authority was that, under subsection (c),

[63] House Comm. Report at 1; *see id.* at 1-2, 16, 28; Sen. Ag. Comm. Report at 2, 29-30; Sen. Commerce Comm. Report at 7, 29-30, 44.

[64] *See* House Comm. Report at 1-2, 12-13; Sen. Ag. Comm. Report at 1-2, 4-6; Sen. Commerce Comm. Report at 8.

[65] Sen. Ag. Comm. Report at 30; Sen. Commerce Comm. Report at 44.

[66] House Comm. Report at 16; *see* id. *at* 1-2 ("State authority to change Federal labeling and packaging is completely preempted.").

[67] *See* Brief in Opposition, No. 03-388, at 7-8.

EPA, not the states, would register pesticides for additional uses to meet local state needs.[68] That provision was not, however, enacted into law, and subsection (c) as enacted preserves the states' authority to register pesticides for additional uses within that state and thereby to impose labeling requirements on such pesticides. Moreover, to the extent that subsection (b) generally precludes the states from imposing labeling "requirements," there is no support for construing that term to preclude any common law damages remedies.

* * *

As the history of the 1972 Act makes clear, the three subsections of Section 136v together address a narrow, albeit important subject in the regulation of pesticides—the ongoing authority of state pesticide-regulating agencies in wake of the expansion of federal pesticide authority effected by the Act. Read together, these parts of Section 136v establish: (a) that state agencies generally may regulate a pesticide's use more strictly than the federal government has chosen to; (b) that, in doing so, states ordinarily cannot impose labeling requirements; and (c) states may impose their own labeling requirements in registering pesticides for special local needs. There is no basis for concluding that, in delineating the ongoing authority of the state agencies, Congress had any intent to eliminate any common law damages remedies.

CONCLUSION

The judgment of the court of appeals should be reversed.

[68] *See* House Comm. Report at 16 ("With regard to this Federal preemption of labeling and packaging, EPA may, where appropriate, in setting labeling and packaging requirements, give consideration to regional, State, and local needs.").

Respectfully submitted,

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